IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA, *ex rel.* ELAINE BENNETT,	§	
Plaintiffs,	§	
V.	§	CIVIL ACTION NO. H-07-2467
BOSTON SCIENTIFIC CORPORATION and GUIDANT CORPORATION,	§	
Defendants.	§	

MEMORANDUM AND OPINION

This case is one of a number raising the question of when a manufacturer's promotion of a medical device for an "off-label" use may provide the basis for a *qui tam* action by a private plaintiff suing under the False Claims Act.[1] The relator, Elaine Bennett, alleges that Boston Scientific Corporation and Guidant Corporation improperly promoted the FlexView microwave surgical-ablation system for an off-label use and that these promotional activities caused physicians and hospitals to submit false claims for reimbursement from Medicare or Medicaid. The FDA has approved the defendants' microwave surgical-ablation system for the general uses of ablating soft tissue and striated, cardiac, and smooth muscle. The relators allege that the defendants have improperly promoted the device for the off-label use of surgical ablation to treat atrial fibrillation, both in conjunction with other cardiac surgery and as a stand-alone procedure.

The defendants have moved to dismiss under Rule 12(b)(6), applying the standards of Rule 8 and Rule 9(b) of the Federal Rules of Civil Procedure. The defendants argue that the allegations

[1] 31 U.S.C. § 3729 *et seq.*

of off-label promotional activities are insufficient to plead that they caused physicians or hospitals to submit false reimbursement claims to Medicare or Medicaid. (Docket Entry No. 68). Bennett responded, (Docket Entry No. 75), and the defendants replied, (Docket Entry No. 77).

Based on the pleadings, the motion, the responses, and applicable law, this court grants the defendants' motion to dismiss, for the reasons explained in detail in this Memorandum and Opinion. Because there has been only one amendment, and because Rule 15 embodies a liberal amendment policy, the relators may amend no later than April 22, 2011, consistent with this Memorandum and Opinion.

I. Background

A. Procedural History

Elaine Bennett filed her complaint on November 9, 2006, under seal, to allow the United States to decide whether it wanted to intervene.[2] This is one of five *qui tam* actions filed by Elaine Bennett against medical-device manufacturers. (Docket Entry No. 4).[3] The United States has not intervened in this suit, but it has filed a "Statement of Interest in Response to the Defendant's Motion to Dismiss Plaintiff's First Amended Complaint, (Docket Entry No. 73). The relator filed an amended complaint in July 2009, (Docket Entry No. 33), and an unredacted version of that complaint in December 2009, (Docket Entry No. 58).

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[2] A private person may bring an FCA action in the name of the government. 31 U.S.C. § 3730(b). The complaint is served on the government under Federal Rule of Civil Procedure 4(d)(4) and filed *in camera* and under seal for at least sixty days. *Id.* at § 3730(b)(1). The government may elect to intervene and proceed with the action within sixty days after it receives both the complaint and the material evidence and information. *Id.* The relators did not file evidence or information beyond the complaint in this case.

[3] The other qui tam actions are discussed in this court's opinion in *United States ex rel. Bennett v. Medtronic, Inc.*, — F. Supp. 2d —, 2010 WL 3909447 (S.D. Tex. Sept. 30, 2010). This opinion uses much of the analysis from this court's previous opinion.

B. The Parties

Boston Scientific develops, manufactures, and markets medical devices, including surgical devices. On April 21, 2006, it acquired the codefendant, Guidant Corporation and its Cardiac Rhythm Management and Cardiac Surgery Divisions. Before the acquisition, Guidant had developed the FlexView microwave surgical-ablation system. (Docket Entry No. 58, ¶¶ 17–18).

Boston Scientific employed the relator, Elaine Bennett, for a short period — from June 12 to September 28, 2006 — as a sales representative in the Midwest region. Bennett worked in Central Illinois and throughout Missouri. (*Id.*, ¶ 16). In addition to her false claim allegations, Bennett alleges that the defendants retaliated against her for challenging the legality of their marketing practices. (*Id.*, ¶ 128).

C. The False Claims Act

The False Claims Act prohibits the knowing submission of false or fraudulent claims for payment, or causing the submission of such claims, to the federal government, and prescribes fines and treble damages to penalize offenders. 31 U.S.C. § 3729(a). The FCA establishes liability for "[a]ny person who . . . knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval . . . [or] knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government." 31 U.S.C. § 3729(a)(1–2), *amended by* 31 U.S.C. § 3729(a)(1)(A–B).

When a *qui tam* suit is brought by a private relator and the government declines to intervene, the relator is entitled to between 25 and 30% of the recovery, § 3730(d)(2), as well as attorneys' fees. As has often been pointed out, the Act does not create a cause of action against all fraudulent conduct affecting the government. Rather, FCA liability attaches to a "false or fraudulent claim for

payment" or to a "false record or statement [made] to get a false or fraudulent claim paid by the government." 31 U.S.C. § 3729(a)(1)–(2), *amended by* 31 U.S.C. § 37299(a)(1)(A–B). "Evidence of an actual false claim is the '*sine qua non* of a False Claims Act violation.'" *United States ex rel. Clausen v. Lab. Corp. of Am., Inc*., 290 F.3d 1301, 1311 (11th Cir. 2002).

In this case, there are no allegations that the defendants themselves submitted false claims. Instead, the complaint alleges that the defendants knowingly caused the submission of fraudulent claims by physicians and hospitals. The fraudulent claims allegedly seek reimbursement for off-label uses of the defendants' devices. The complaint does not identify any specific false claim presented by others to Medicare/Medicaid. Nor does the complaint identify any entity or person who actually submitted such a claim. Instead, the complaint alleges that as a result of the defendants' marketing campaign and illegal kickbacks, the FlexView microwave surgical ablation system has been widely used for the off-label purpose of treating atrial fibrillation by physicians and hospitals and that this use "caused to be presented to the United States fraudulent claims . . . in order to obtain reimbursement for surgical ablation services performed with Defendants' microwave surgical ablation products." (Docket Entry No. 58, ¶ 132).

D. Off-Label Use of Medical Devices

The FDA approves products for specific indications, which are stated in the label. When a medical device is approved for one purpose or indication and used outside this approved purpose, that use is deemed "off label." Off-label promotion may involve disseminating information about product uses the FDA did not approve. The FDA generally restricts a manufacturer from marketing for off-label purposes but does not restrict a hospital from purchasing, or a doctor from prescribing

or using, a medical device for an off-label purpose. Off-label use of many devices and drugs is an accepted medical practice.[4]

Courts recognize that off-label use of a drug or medical device is not the same as a medically unnecessary use of that drug or device. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S. Ct. 1012, 1018 (2001) ("'[O]ff-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Svidler v. United States Dep't of Health and Human Servs.*, No. C-03-3593 MJJ, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("[T]he FDA can restrict a company from marketing off-label uses, but cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary." (citing *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998)); *United States ex rel. Polansky v. Pfizer*, No. 04-cv-0704 (ERK), 2009 WL 1456582, at *6 (E.D.N.Y. May 22, 2009) ("[T]he FDA has acknowledged that 'accepted medical practice often includes drug use that is not reflected in approved drug labeling.'" (citing Food & Drug Admin., Use of Approved Drugs for Unlabeled Indications, 12 FDA Drug Bulletin 4, 5 (1982)); *United States ex rel. Stephens v. Tissue Sci. Labs., Inc.*, Civil Action No. 1:07-CV-2357-ODE, LEXIS 2009 DIST. 101601, at *20 (N.D. Ga. Aug. 13, 2009) (noting that DRG payment may be made for hernia care even if noncovered care — the use of the device at issue — was present).

Medicare reimbursement for off-label uses of medical devices is not addressed within the Medicare Act itself. *See generally Yale–New Haven Hosp. v. Leavitt*, 470 F.3d 71, 73 (2d Cir.

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[4] *See generally*, Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail*, 61 FOOD AND DRUG L.J. 653, 655–56 (2006).

2006). Broad wording excludes from Medicare coverage "any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Secretary of the Department of Health and Human Services "is responsible for specifying those services that are covered under the 'reasonable and necessary' standard" and "has wide discretion in selecting the means for doing so." *Yale–New Haven Hosp.*, 470 F.3d at 74 (citing 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984)). Traditionally, the Secretary has acted through "formal regulations and (informal) instructional manuals and letters." *Id.* Before 1995, the Medicare Hospital Manual, the Medicare Carriers Manual, and the Intermediary Manual stated that payment could not be made for devices not approved by the FDA for commercial distribution because "they were not considered 'reasonable and necessary' under 42 U.S.C. § 1395y(a)(1)." *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 323 (D. Conn. 2004) (citing Medicare Hospital Manual § 260.1(B) (effective July 15, 1986); Medicare Carriers Manual § 230.1; Intermediary Manual § 3151.1)); *see also Yale–New Haven Hosp.*, 470 F.3d at 74 (discussing the history of the manual provisions). In 1995, the Secretary of the United States Department of Health and Human Services published regulations superseding the manual provisions and allowing Medicare coverage for Category B investigational devices under the "reasonable and necessary" standard. *Yale–New Haven Hosp.*, 470 F.3d at 71. As one court has summarized:

> On September 19, 1995, after completing a formal notice-and-comment rule-making process regarding coverage for investigational devices under the statutory 'reasonable and necessary' standard, the Secretary of HHS published final regulations addressing the coverage of medical devices categorized by the FDA as 'investigational.' The new regulations provided Medicare coverage for those 'non-experimental/investigational' devices as to which the initial questions about the devices' safety and effectiveness had been resolved. *See* 42

> C.F.R. §§ 405.201(b), 405.203, 405.211(b). In contrast to the total exclusion from coverage of such devices under the Manual provision, the new regulations classified such devices as either experimental/investigational ('Category A') for which there continued to be no coverage, or non-experimental investigational ('Category B') which are eligible for Medicare coverage. *See* 42 C.F.R. §§ 405.201, 405.203(a), 405.205, 405.209, 405.211.

In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 325 (D. Conn. 2004).

The allegations in this case are that a Category B non-experimental/investigational medical device the FDA approved for a general use — ablating soft tissue and striated, cardiac, and smooth muscle in surgical procedures — is being marketed for a specific use that the FDA has not approved — to ablate cardiac tissue to treat atrial fibrillation. Atrial fibrillation is a fast and irregular beating of the heart's atria. The first-line treatments for atrial fibrillation are nonsurgical and include using drugs. (Docket Entry No. 58, ¶ 46–47). According to the relator, a recognized surgical treatment is an open-heart procedure known as the "maze." In a maze procedure, a cardiothoracic surgeon makes strategic incisions in both atria and uses a "cut and sew" technique to repair the heart. The maze procedure is effective but also dangerous and difficult. (*Id.*, ¶ 48). As a result, the medical community has continued efforts to find less invasive, more effective methods of treatment.

Two newer forms of treatment for atrial fibrillation are catheter ablation and surgical ablation. In catheter ablation, an electrophysiologist — a specialized cardiologist — threads a catheter through the patient's leg and into the heart. The catheter is equipped with a device that delivers microwaves to ablate heart tissue. The relator alleges that catheter ablation is often an outpatient procedure. (*Id.*, ¶¶ 50–52). The relator alleges that a large number of studies and scientific organizations have recently recognized catheter ablation as an effective procedure to treat atrial fibrillation. In 2006, catheter ablation was included within the "Guidelines" for treating atrial

fibrillation as a "third-tier treatment option, following drug therapy and cardioversion." (*Id.*, ¶¶ 52–53).

The relator alleges that surgical ablation is a more recent method. Surgical ablation treats atrial fibrillation by using microwaves to ablate heart tissue and disrupt the normal pathways for electrical impulses. (*Id.*, ¶¶ 54–55). It is typically an inpatient procedure performed by cardiothoracic surgeons. It can be performed as an additional procedure during open-chest surgery for other cardiac conditions or as a stand-alone procedure. As part of other open-chest procedures, a surgeon uses the ablation device to make incisions on tissue similar to the incisions made in a "maze" procedure. In a stand-alone surgical ablation, a surgeon makes incisions on a patient's chest and directs an ablation device through those incisions to the heart. According to the relator, stand-alone surgical ablation, "unlike traditional open heart surgery — does not require opening the thoracic cavity to expose the heart and lungs and does not require putting the patient on a heart-lung bypass machine to stop the heart." (*Id.*, ¶ 59). It is an inpatient but minimally invasive surgery.

As the relator acknowledges, the FlexView system is classified for Medicare reimbursement purposes as a Class II device. (*Id.*, ¶ 73); *see also* 21 C.F.R. § 878.4400 (identifying "electrosurgical cutting and coagulation device and accessories . . . intended to remove tissue and control bleeding by use of high-frequency electrical current" as a Class II device). Under Medicare regulations, a device "believed to be in . . . Class II" is a Category B — "non-experimental/investigational" — device. 42 C.F.R. § 405.201(b). Class II devices "require special controls, such as performance standards or postmarket surveillance, to provide reasonable assurance of safety and effectiveness." 42 C.F.R. § 405.201(b). Medicare contractors may approve coverage for Category B devices. *Id.* at § 405.211(b). The relator acknowledges that there is no "[n]ational [c]overage [d]etermination"

for reimbursement for microwave surgical ablation. "Accordingly, the Medicare Carrier in each state or region determines the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation." (Docket Entry No. 58, ¶ 65). While there is no FDA approval for using the FlexView system to treat atrial fibrillation, there is no identified statutory, regulatory, or other prohibition on reimbursement to physicians or hospitals for using the FlexView system for this purpose. While Medicare and Medicaid typically do not reimburse off-label prescriptions for drugs, *see United States ex rel. Franklin v. Parke–Davis*, 147 F. Supp. 2d 39, 44–45 (D. Mass. 2001); *United States ex rel. Hess v. Sanofi–Synthelabo Inc.*, No. 4;05CV570MLM, 2006 WL 1064127, at *10 (E.D. Mo. Apr. 21, 2006), the relator has not pointed to a similar categorical restriction on reimbursement for Category B medical devices.[5] For medical devices, eligibility for reimbursement

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[5] Under the FDCA, new pharmaceuticals cannot be distributed in interstate commerce unless the drug's sponsor satisfies the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Once a drug is approved for a particular use, the FDA does not prevent doctors from prescribing the drugs for uses that are different than those approved by the FDA. *Parke–Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001) (citing *Buckman*, 121 S. Ct. at 1018). However, "[w]hether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program." *Id.* One court has summarized the drug-reimbursement criteria, as follows:

> Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* § 1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. *Id.* § 1396r-8(k)(6). *See also id.* § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

United States ex rel. Franklin v. Parke–Davis, 147 F. Supp. 2d 39, 44–45 (D. Mass. 2001).

depends on whether the procedure performed is "medically necessary" or "reasonable and necessary."

E. The Medicare Billing System

The Medicare billing scheme is the context for this FCA suit. Medicare prepays hospitals specific predetermined amounts based on codes for the diagnosis and procedure performed. (Docket Entry No. 58, ¶¶ 25, 28). The complex billing scheme includes a lengthy list of codes that reflect medical and administrative judgments.

The amounts hospitals receive for inpatient procedures depend on the Diagnosis Related Group ("DRG") code assigned to a patient. In addition to basic information about the patient and the diagnosis, the procedure performed on the patient is a factor in determining a patient's DRG. 42 C.F.R. § 412.60(c)(1) (stating that the DRG is based on "essential data extracted from the inpatient bill for that discharge" including "the patient's age, sex, principal diagnosis, . . . secondary diagnoses, procedures performed, and discharge status"). Hospitals enter a procedure code when they submit Form HCFA-1450 (UB-92) to obtain reimbursement for items and services provided to a patient. *Cardiac Devices.*, 221 F.R.D. at 328–29; *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 58, 91–92 (D. Conn. 2006). These codes are based on the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system. (Docket Entry No. 58, ¶ 27). In addition to Forms UB-92, hospitals annually submit a Hospital Cost Report, Form HCFA-2552, which summarizes the amounts of interim payments received and the amounts the hospital claims from Medicare. *Cardiac Devices.*, 221 F.R.D. at 328–29

The amounts Medicare pays physicians for services provided in conjunction with a procedure performed at a hospital are based on Current Procedural Terminology ("CPT") codes published by

the American Medical Association. Physicians typically provide the CPT code and submit claims for payment on Form CMS-1500. (Docket Entry No. 58, ¶¶ 29–33, 37).

F. The Medical Device at Issue

The FlexView system includes a microwave generator a surgical-ablation probe "that delivers a continuous flow of microwave energy from the generator to the cardiac tissue" and "is designed to ablate tissue by the induction of cell death in targeted areas." (*Id.*, ¶ 60). The FlexView system can be used either in conjunction with other cardiac surgical procedures or for stand-alone surgical ablation. As noted, the FDA has approved the defendants' FlexView system for use in "the surgical ablation of soft tissue, and striated, cardiac, and smooth muscle." (*Id.*, ¶ 74). The FDA has denied general approval for the FlexView system as a treatment for atrial fibrillation.[6] (*Id.*, ¶ 79). The relator alleges, and the defendants accept as true for the purpose of this motion, that because the FDA has approved the FlexView system for general use and has not approved the FlexView system for treating atrial fibrillation, the defendants may not market the FlexView system for use in minimally invasive closed-chest surgical procedures for treating atrial fibrillation. (*Id.*, ¶ 81); *see* 21 C.F.R. § 812.7(a).

G. The Alleged Improper Promotional Activities

The relator alleges four categories of what she characterizes as actionable conduct by the defendants promoting off-label use of the FlexView system.

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[6] At the time of the third amended complaint, Boston Scientific was engaged in a study about the FlexView system's efficacy in the treatment of atrial fibrillation. The study is called "RESOLVE-AF" (Randomized Study of Surgical Ablation with Microwave Energy for the Treatment of Atrial Fibrillation). (Docket Entry No. 58, ¶ 77).

- The defendants instructed their sales representatives to train doctors to use the FlexView system to treat atrial fibrillation. Newly hired sales representatives were given a "ten-day 'New Hire Training' that focuses on using the [FlexView system] to treat atrial fibrillation." During the training, the defendants gave their new hires a document outlining "seven basic steps" for using the FlexView system to treat atrial fibrillation. Before the training's conclusion, the defendants required new hires to demonstrate an ability to "teach" physicians how to use the system to treat atrial fibrillation. The defendants required its sales representatives to accompany surgeons into the operating room and instruct them on using the system to treat atrial fibrillation. The defendants also used "'Ablation Account Managers' who focused entirely on training surgeons to perform microwave surgical ablation to treat atrial fibrillation." (Docket Entry No. 58, ¶¶ 83–87).
- The defendants marketed the FlexView system to hospitals by emphasizing the high reimbursement-to-cost ratio available through using surgical ablation to treat atrial fibrillation in minimally invasive procedures. This is part of the "upcoding" allegations set out below. The defendants' promotional material emphasized the opportunity to obtain a favorable reimbursement-to-cost ratio. The promotional materials stated that there was a seven billion dollar market for reimbursements for the treatment of atrial fibrillation and that hospitals could receive approximately $5,000.00 per treatment by using the FlexView System to treat atrial fibrillation even when the costs to the hospital were far lower. The defendants also trained its sales representatives to "market the spread." The defendants instructed sales

representatives to ask hospital executives, "Would you like to learn about a procedure with a large, untreated patient pool and favorable reimbursement"; provided sales representatives with powerpoint presentations emphasizing favorable reimbursements; and instructed sales representatives "to 'go after' hospitals who have a 'CEO and administration that understands the clinical and economic landscape.'" (Docket Entry No. 58, ¶¶ 88–93).

- The defendants instructed their sales representatives to market the FlexView system by advising hospitals to "upcode" Medicare billings. The allegation is that Medicare could be billed for using the FlexView system using a DRG and procedure code for open-chest surgery.[7] The relator alleges that the defendants told sales representatives to tell hospitals that in closed-chest stand-alone atrial fibrillation procedures, they could bill Medicare using DRG 108 (excision or destruction of other lesion or tissue of heart, open approach), which is a code for "open-chest" procedures. The relator acknowledges that the DRG code associated with procedure code 37.33 is DRG 108. The relator alleges that the ICD-9 procedure code and the DRG codes are incorrect when used for closed-chest procedures. The relator alleges that because there is no procedure code that provides reimbursement for the closed-chest surgical ablation, "a more appropriate code . . . would be procedure code 37.99 (other operations on heart and pericardium)," and DRG 110 or 111 (respectively, major cardiovascular

[7] The relator's upcoding allegations appear to be directed at hospitals. (Docket Entry No. 58, ¶ 116). In describing Medicare billing procedures, the amended complaint alleges that hospitals use ICD-9-CM codes for billing, (*Id.*, ¶ 27) and that physicians use CPT codes, (*Id.*, ¶¶ 29–33, 37). The upcoding allegations appear to be focused on the upcoding of the ICD-9-CM code entered by the hospitals. (*Id.*,¶ 118).

procedures with and without complications and comorbidities). (*Id.*, ¶ 122). The relator alleges that the average reimbursement for a hospital under DRG 108 is $30,289 and the average cost to the hospital for patients who require procedures qualifying under that DRG is $31,074. In contrast, the average cost to the hospital of a closed-chest stand-alone surgical ablation is $10,650. The relator alleges that by training sales representatives to tell hospitals that they could bill Medicare for closed-chest stand-alone procedures using DRG and procedure codes for open-chest procedures, the defendants improperly promoted its FlexView system. (*Id.*, ¶¶ 116–24). This category of alleged actionable promotion by the defendants applies only to stand-alone procedures. The relator does not allege that the use of the FlexView in open-chest procedures that also treat other cardiac conditions is improperly billed using the codes for such procedures.

- The relator also alleges that the defendants provided remuneration to physicians and hospitals to encourage them to use the FlexView system, in violation of the antikickback statute, 42 U.S.C. § 1320a-7b(b). The relator alleges that the defendants provided in-kind services to physicians, particularly cardiothoracic surgeons, including referral services, marketing, and direct payments. (Docket Entry No. 58, ¶¶ 99–100). The relator alleges that the defendants sponsored meetings to screen candidates for surgical ablation and referred them to cardiothoracic surgeons who used the FlexView system. (*Id.*, ¶ 103). The relator alleges that the defendants sponsored dinner programs and letter-writing services to present information about FlexView to primary care physicians who could make referrals. (*Id.*, ¶ 102). The

> relator alleges that the defendants also helped cardiothoracic surgeons advertise surgical ablation to treat atrial fibrillation, including producing marketing brochures that identified physicians who used the FlexView system to treat atrial fibrillation. (*Id.*, ¶ 104). Finally, the relator alleges that the defendants provided direct payments to physicians in the form of grants to physicians who promoted the FlexView system to other physicians. (*Id.*, ¶¶ 105). As to hospitals, the relator alleges that the defendants paid kickbacks in the forms of loans to purchase the FlexView equipment contingent on a minimum number, free products, such as generators to power FlexView components and disposable equipment used to perform surgical ablations, and discounts on other products contingent on a hospital's commitment to purchase a fixed number of ablation products. The relator alleges that the defendants offered these inducements on the condition that a hospital use the FlexView system for at least eighty percent of surgical ablation procedures. (*Id.* at ¶¶ 106–15). The relator alleges that the defendants' kickbacks caused false or fraudulent claims for payment to be submitted because certification of compliance with all applicable laws and regulations, including the antikickback statute, is a condition for payment under Medicare.

The relator alleges that these promotional efforts "caused physicians and hospitals to perform an increased number of costly inpatient surgical ablation procedures in cases where less costly and less invasive treatments otherwise have been performed." (*Id.*, ¶ 131). The relator alleges that the defendants "knowingly made, used, and caused to be made and used false records and statements

in order to obtain reimbursement from the United States for surgical ablation services performed with Defendants' microwave surgical ablation products." (*Id.* at ¶ 133).

The relator also alleges that the defendants violated the FCA's antiretaliation provisions. She alleges that she engaged in "protected conduct [that] put the Defendants on notice of the distinct possibility of a qui tam action" and that the defendants harassed her, threatened her, and ultimately discharged her. (*Id.*, ¶ 139–41). She also alleges that these acts violated Illinois law. (*Id.*, ¶¶ 142–46).

In their motion to dismiss under Rule 12(b)(6), the defendants argue that the relator has not alleged that they made any false claim or caused any false claim to be submitted to Medicare. The defendants emphasize both that the complaint does not link their marketing practices to the submission of specific false claims and that their promotional tactics are not "material" to the government's decisions to pay Medicare claims for surgical ablations. The defendants also argue that the relator did not allege sufficient facts to support a reasonable inference that hospitals or physicians falsely certified compliance with the antikickback statute. Finally, the defendants argue that the relator has not met Federal Rule of Civil Procedure 9(b)'s pleading requirements for fraud because she fails to identify the "who, what, when, where, and how of the alleged fraud." *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997).

As to the FCA retaliation claims, the defendants argue that the relator failed to allege sufficient facts supporting her allegations. Specifically, the defendants argues that the relator has not alleged facts showing that she had engaged in a protected activity, that the defendants were aware she had engaged in a protected activity, or that her discharge was motivated by that protected

activity. As to the Illinois retaliation claims, the defendants argue that Illinois law does not govern her allegations. Alternatively, the defendants argue that she has failed to plead sufficient facts supporting her state law claim.

The relator responds that the defendants' promotional efforts caused physicians and hospitals to perform more surgical ablations to treat atrial fibrillation than would otherwise have been performed and, as a result, more that were not medically necessary. *See* Docket Entry No. 75, at 9 ("[C]laims for reimbursement would not have been submitted to the Government *but for* Defendants' off-label promotion of medically unnecessary surgical ablation procedures using their Flex surgical ablation system."). As a result, physicians and hospitals submitted claims for reimbursement for procedures that were not medically necessary and that would not have been submitted but for the off-label promotion. *See* Docket Entry No. 75, at 9; 42 U.S.C. § 1320c-5(a)(3) ("medically necessary"); 42 U.S.C. § 1395y(a)(1)(A) ("reasonable and necessary"). The relator argues that using the FlexView system to treat atrial fibrillation is *never* medically necessary because the system is not FDA approved, is experimental, and is not a first-line treatment for this purpose. The relator also argues that by marketing hospitals' ability to upcode stand-alone ablation procedures using the FlexView system, the defendants were the "but for" cause of hospitals and doctors submitting claims for payment with three false statements: that the code used accurately represented the procedure performed; that the procedure was the most economical, as required by 42 U.S.C. § 1320c-5(a)(1); and that the procedure was "medically necessary," as required by 42 U.S.C. § 1320c-5(a)(3). The relator also argues that the defendants' kickbacks caused physicians and hospitals falsely to certify — either implicitly in claims for payment, or expressly in annual compliance statements — compliance with the antikickback statute. The relator argues that the

defendants' promotional efforts were material because their "natural tendency" was to cause the submission of false claims. Finally, the relator responds that she has provided sufficient factual allegations to meet the Rule 9(b) requirements for pleading a scheme to defraud.

Each argument and response is analyzed below.

II. The Legal Standards for a Motion to Dismiss

The defendants moved under Rule 12(b)(6) to dismiss the allegations based on the alleged off-label promotion of the FlexView devices, the allegations of the antikickback statute in connection with the sale of these devices, and the retaliation allegations. Because FCA claims are fraud claims subject to the Rule 9(b) pleading requirements, *see Hopper v. Solvay Pharms.*, 588 F.3d 1318, 1325 (11th Cir. 2009); *Thompson*, 125 F.3d at 903; *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 468 (5th Cir. 2009), the defendants also moved to dismiss for failure to comply with these requirement. The parties also analyzed the application of 31 U.S.C. § 3729(a).

A. Rule 12(b)(6)

Rule 12(b)(6) allows dismissal if a plaintiff fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), the Supreme Court confirmed that Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). To withstand a Rule 12(b)(6) motion, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct

alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). "To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief—including factual allegations that when assumed to be true 'raise a right to relief above the speculative level." *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (footnote omitted) (quoting *Twombly*, 550 U.S. at 555); *see also S. Scrap Material Co. v. ABC Ins. Co.* (*In re S. Scrap Material Co.*), 541 F.3d 584, 587 (5th Cir. 2008) (quoting *Twombly*, 550 U.S. at 555), *cert. denied*, 129 S. Ct. 1669 (2009). "Conversely, 'when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Cuvillier*, 503 F.3d at 401 (quoting *Twombly*, 550 U.S. at 558).

When a plaintiff's complaint fails to state a claim, the court should generally give the plaintiff at least one chance to amend under Rule 15(a) before dismissing with prejudice. *See Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002) ("[D]istrict courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."); *see also United States ex rel. Adrian v. Regents of the Univ. of Cal.*, 363 F.3d 398, 403 (5th Cir. 2004) ("Leave to amend should be freely given, and outright refusal to grant leave to amend without a justification . . . is considered an abuse of discretion." (internal citation omitted)). However, a plaintiff should be denied leave to amend a complaint if the court determines that "the proposed change clearly is

frivolous or advances a claim or defense that is legally insufficient on its face . . . ." 6 CHARLES A. WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1487 (2d ed. 1990); *see also Ayers v. Johnson*, 247 F. App'x 534, 535 (5th Cir. 2007) (unpublished) (per curiam) ("'[A] district court acts within its discretion when dismissing a motion to amend that is frivolous or futile.'" (quoting *Martin's Herend Imports, Inc. v. Diamond & Gem Trading United States of Am. Co.*, 195 F.3d 765, 771 (5th Cir. 1999)).

B. Rule 9(b)

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b). "At a minimum, Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud." *Thompson*, 125 F.3d at 903 (quoting *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 179 (5th Cir. 1997)). The pleader must "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Williams*, 112 F.3d at 177. "'Rule 9(b)'s ultimate meaning is context specific, and thus there is no single construction of Rule 9(b) that applies in all contexts.'" *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009) (quoting *Williams*, 112 F.3d at 178). In the context of the FCA, the parties dispute whether it is appropriate to relax the Rule 9(b) standard. The relator acknowledges that she has failed to identify a specific false claim but argues that this should not be required because the facts relating to the alleged fraud are "peculiarly within the perpetrator's knowledge" and the alleged fraud occurred over a multi-year period. (Docket Entry No. 75, at 25–27). The defendants respond that, to the contrary, the relevant information on billing and reimbursements are in the hands of third

parties, including physicians, hospitals, and Medicare, and that there is no basis in the case law to relax the Rule 9(b) requirements in such circumstances. (Docket Entry No. 77, at 11–15).

III. The False Claims Act

In *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, the Fifth Circuit adopted a four-prong test for § 3729(a) claims. 575 F.3d 458 (5th Cir. 2009). The Fifth Circuit requires: "(1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys."[8] *Id.* at 467 (adopting the test stated in *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008)).

A. Which Version of the FCA Applies?

A threshold issue is whether the amended or earlier version of 31 U.S.C. § 3729 applies. The Fraud Enforcement Recovery Act of 2009 (FERA) amended sections of the False Claims Act, including two subsections implicated in this action, 31 U.S.C. § 3729(a)(1) and (2).[9] Pub. L. No.

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[8] In *Longhi*, the Fifth Circuit did not state whether this four-prong test applies to the version of the FCA amended by 31 U.S.C. § 3729(a)(1)(B), the "post-FERA version." For post-FERA claims, the fourth prong — that the statement "cause the government to pay out money or forfeit money" — may need alteration. The post-FERA FCA does not require that the government actually pay the false claim. *Compare* 31 U.S.C. § 3729(a)(2), *amended by* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim *paid or approved by the government*.") (emphasis added); *with* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false fraudulent claim"). The application of pre- and post-FERA versions of the FCA is analyzed below, but the elements of a false statement, scienter, and materiality are unaffected. 31 U.S.C. 3729(a)(1)(A–B).

[9] The relator also alleged that the defendants violated 31 U.S.C. § 3729(a)(7), *amended by* 31 U.S.C. § 3729(a)(1)(G). Section 3729(a)(7) establishes liability for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." In their briefing, the relator appears to focus on allegations involving sections (a)(1) and (a)(2) and does not argue that section (a)(7) demands a different

111-21, § 386, 123 Stat. 1617 (2009). FERA became law on May 20, 2009. It contained a retroactivity provision stating as follows:

> The amendments made by this section shall take effect on the date of enactment of this Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1) of title 31, United States Code, as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 *et seq*.) that are pending on or after that date.

123 Stat. 1617 § 4(f). For the § 3729(a)(1) claim, this court must apply the pre-FERA version of § 3729(a)(1) because the relator filed this suit in November 2006, before the "date of [FERA's] enactment." Section 4(f)'s exception — "subparagraph (B) of section 3729(a)(1)" — applies to the § 3729(a)(2) claim. Section 4(f) states that the amended version of subsection (a)(2), now found at 31 U.S.C. § 3729(a)(1)(B), applies to all "claims" under the FCA pending on or after June 7, 2008. The pre- and post-FERA versions of the FCA define "claim" similarly. The pre-FERA FCA defines claim as

> [A]ny request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, guarantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(c), *amended by* 31 U.S.C. § 3729(b)(2). The post-FERA amendments define "claim" as "any request or demand, whether under a contract or otherwise, for money or property . . . [that] is presented to an officer, employee, or agent of the United States . . . ." 31 U.S.C. §

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analysis. Though this opinion refers explicitly only to (a)(1) and (a)(2), its analysis is applicable to (a)(7) to the extent the relator asserts (a)(7) provides a basis for liability.

3729(b)(2). Neither definition refers to *cases* or causes of action under the FCA. Instead, both definitions refer to claims "for money or property" from the government. Because "claim" is a defined term in the FCA, the reference to "claims" in FERA § 4(f)(1) must be read in accordance with that definition. *See United States ex rel. Gonzales v. Fresenius Med. Care N. Am.*, No. EP-07-CV-247-PRM, 2010 WL 1645971, at *9 (W.D. Tex. Mar. 31, 2010) (reaching the same conclusion). Under this approach, the post-FERA version of § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), applies if the false claims alleged by the relator were pending on or after June 7, 2008.

Most of the district courts that have ruled on this issue have reached the same conclusion. *See, e.g., United States ex rel. Compton v. Circle B Enters., Inc.*, No. 7:07-CV-32, 2010 WL 942293, at *2 n.5 (M.D. Ga. Mar. 11, 2010) ("The revised version of section (a)(1)(B) does not apply to this case because none of Defendants' claims (the . . . reimbursement claims) at issue here were pending on or after June 7, 2008."); *United States ex rel. Putnam v. E. Idaho Reg'l Med. Ctr.*, No. CIV. 4:07-192, 2010 WL 910751, at *4 (D. Idaho Mar. 10, 2010) ("[B]ecause the claims for Medicaid reimbursement at issue in this case were neither pending on nor filed after June 7, 2008, the pre-FERA version of § 3729(a)(2) governs . . . ."); *Mason v. Medline Indus., Inc.*, No. 07-C-5615, 2010 WL 653542, at *3 (N.D. Ill. Feb.18, 2010) ("The court interprets § 4(f)(1) to apply to 'claims' as defined in the FCA. Accordingly, FERA's amendment does not apply retroactively to this case."); *United States ex rel. Sanders v. Allison Engine Co., Inc.*, 667 F. Supp. 2d 747, 752 (S.D. Ohio 2009) ("[T]he clear indication from Congress is that the revised language at issue here is applicable to 'claims' pending on June 7, 2008, and not to 'cases' pending on June 7, 2008. Since the Defendants in this case had no 'claims' pending on June 7, 2008, the retroactivity clause does not apply to them . . . ."); *United States v. Sci. Applications Int'l Corp.*, 653 F. Supp. 2d 87, 107

(D.D.C. 2009) ("[S]ection 4(f)(1) will be interpreted to apply to 'claims' as defined in § 3729, that is, requests or demands for money or property. Thus, FERA has no impact on the present action.").

The relator's amended complaint does not appear to involve claims pending on or after June 7, 2008. The amended complaint refers to 31 U.S.C. § 3729(a)(2), not 31 U.S.C. § 3729(a)(1)(B). The relator's allegations of unlawful promotional tactics date back to 2006 when she was employed by Boston Scientific. (Docket Entry No. 58, ¶ 16). The relator's allegations of false or fraudulent claim submission could, however, involve claims submitted after June 7, 2008. The defendants have pointed out that the FCA has been amended, (Docket Entry No. 68, at 4 n.5). The relator has not argued whether the amended FCA or the prior version applies to their claims. The defendants argue that the result is the same under either version and the relator has not addressed this issue. (*Id.*).[10] In an abundance of caution, the analysis is conducted under both versions of the FCA because the amended complaint may cover claims pending on or after June 7, 2008.[11]

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[10] Some courts have held that FERA's retroactivity clause is unconstitutional. *E.g.*, *United States ex rel. Sanders v. Allison Engine Co., Inc.*, 667 F. Supp. 2d 747, 755 (S.D. Ohio 2009) (finding that application of the retroactivity clause violates the Constitution's Ex Post Facto Clause, U.S. CONST. art. 1, § 9, cl. 3). The Fifth Circuit has not ruled on this issue. *See United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 470 (5th Cir. 2009) (declining to rule on whether FERA applies retroactively). Neither party raised this issue and it is not necessary to address because the result is the same under either the pre- or post-FERA version of the FCA.

[11] As the analysis makes clear, in this litigation, there is no material difference between pre- and post-FERA versions of § 3729(a)(1). FERA removed § 3729(a)(1)'s requirement that the claim be presented "to an officer or employer of the United States Government or a member of the Armed Forces of the United States." *Compare* 31 U.S.C. § 3729(a)(1), *amended by* 31 U.S.C. § 3729(a)(1)(A) (establishing liability for "any person who . . . knowingly presents or causes to be presented, *to an officer or employee of the United States government or a member of the Armed Forces of the United States*, a false or fraudulent claim for payment or approval." (deleted language italicized)); *with* 31 U.S.C. § 3729(a)(1)(A) (establishing liability for "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"). The defendants do not contest that the reimbursement claims were presented to the government. Similarly, the differences between the pre- and post-FERA versions of § 3729(a)(2) do not affect this litigation. FERA removed § 3729(a)(2)'s requirement that the alleged false claim be "paid or approved by the government." *Compare* 31 U.S.C. § 3729(a)(2), *amended by* 31 U.S.C. § 3729(a)(1)(B) (establishing

B. The Elements of An FCA Claim

1. A False or Fraudulent Claim

The Supreme Court has cautioned that the FCA does not punish every type of fraud committed on the government. *See United States v. McNinch*, 356 U.S. 595, 599 (1958). "The [FCA] attaches liability, not to the underlying fraudulent activity, but to the 'claim for payment.'" *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266–67 (9th Cir. 1996) (finding on summary judgment that violation of Individuals with Disabilities Education Act regulations is not also an FCA violation unless compliance certification is a prerequisite to receive federal funds); *see also United States ex rel. Siewick v. Jamieson Sci. And Eng., Inc.*, 214 F.3d 1372, 1376–77 (D.C. Cir. 2000) (upholding district court's determination on summary judgment that even if the defendants had violated 18 U.S.C. § 207, "a criminal statute aimed at 'revolving door' abuses by former government employees," there was no fact issue as to an FCA violation because defendants were not required to certify compliance with the statute); *United States ex rel. Willard v. Humana Health Plan of Tex Inc.*, 336 F.3d 375, 382–83 (5th Cir. 2003) (upholding district court's dismissal because

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liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government."); *with* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false fraudulent claim"). The defendants do not dispute that the government paid or approved the reimbursement claims. FERA also added a materiality requirement to § 3729(a)(2). *See* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false fraudulent claim") (emphasis added). This change does not affect this litigation because the Fifth Circuit required "material" false statements before the FERA amendments to § 3729(a)(2). *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 470 (5th Cir. 2009). And the post-FERA version of § 3729(a)(2) and the Fifth Circuit both use the same test for materiality. 31 U.S.C. § 3729(b)(4) ("[M]aterial means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."); *Longhi*, 575 F.3d at 470 (adopting the "natural tendency test," which only requires "that the false or fraudulent statements have the potential to influence the government's decisions," and noting the test's consistency with FERA).

the plaintiff only alleged violations of HMO enrollment antidiscrimination laws but did not allege that the United States "conditioned payment . . . on any implied certification of compliance with the anti-discriminatory provisions"); *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009) (upholding district court's dismissal because the plaintiff alleged violations of the FDA medical-device-reporting regulations by selling defective products but did not allege that certification with these regulations was a prerequisite to payment).

In the specific context of reimbursement claims for using a drug or device in a way that violates the FDA, the courts have held that the "mere fact" of "violating FDA regulations does not translate into liability for causing a false claim to be filed." *United States ex rel. Polansky v. Pfizer*, No. 04-cv-0704, 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009); *see also United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 729, 732 (1st Cir. 2007), *overruled on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008) (noting that the alleged marketing practices, "while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement"); *Thompson*, 125 F.3d at 902 ("[C]laims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA.").

The courts have held that a claim may be false or fraudulent under the FCA because it includes a certification of compliance with a federal statute, regulation, or contract that is a prerequisite to obtaining the government benefit. *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 497 (S.D. Tex. 2003), *aff'd*, 111 F. App'x 296 (5th Cir. Oct. 20, 2004). Such "legally false" certification differs from "factually false" certification, which involves an incorrect description of goods or services provided or a request for reimbursement for goods or

services never provided. *See Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). The Fifth Circuit has held that a claim is "legally false" only when a party affirmatively and explicitly certifies compliance with a statute or regulation and the certification is a condition to receiving the government benefit. *See Thompson*, 125 F.3d at 902. In addition to express certifications of compliance, other circuits have found that FCA liability may exist under an "implied theory" of certification. *See Willard*, 336 F.3d at 82 (discussing cases). "The theory of implied certification rests on the notion that 'where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent.'" *United States ex rel. Foster v. Bristol–Myers Squibb Co.*, 587 F. Supp. 2d 805, 823 (E.D. Tex. 2008) (citing *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003)). For example, the Sixth Circuit has found that FCA liability "can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned." *Willard*, 336 F.3d at 82 (quoting *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002)). The Fifth Circuit has never adopted implied certification as a theory of FCA liability. *United States ex rel. Marcy v. Rowan Cos., Inc.*, 520 F.3d 384, 389 (5th Cir. 2008) (citing *Willard*, 336 F.3d at 381–82); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 679 (5th Cir. 2003) (en banc) (Jones, J. concurring); *United States ex rel. Steury v. Cardinal Heath, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010). Instead, the Fifth Circuit has held that "[t]he violation of the statute or regulation does not create a cause of action under the False Claims Act; liability arises only if the defendant has made a false certification of compliance with

the statute or regulation, when payment is conditioned on that certification." *Graves*, 284 F. Supp.2d at 497.

2. Materiality

Liability under both the pre- and post-FERA versions of the FCA requires that an actionable false statement be "material." *Longhi*, 575 F.3d at 467 (citing *Thompson*, 125 F.3d at 899); *see also Allison Engine Co., Inc. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2126 (2008) (explaining that a § 3729(a)(2) "plaintiff must prove that the defendant intended that the false statement be material to the Government's decision to pay or approve the false claim"). The Fifth Circuit applies the "natural tendency" test to determine materiality. *Longhi*, 575 F.3d at 470. This test asks whether "the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even if this is a result of indirect or intangible actions on the part of the Defendants." *Id.* "All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the government's decisions." *Id.*

3. Knowingly

An FCA claim must allege that the false statements were "knowingly" made or caused to be made. The FCA defines "knowing or knowingly" to mean "that a person, with respect to information," (i) "has actual knowledge of the information"; (ii) "acts in deliberate ignorance of the truth or falsity of the information"; or (iii) "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1–3). Because an FCA claim alleges a fraudulent or false statement knowingly made or caused to be made, *Longhi*, 575 F.3d at 468, "[c]laims brought under the FCA must comply with Rule 9(b)." *Thompson*, 125 F.3d at 903 (5th Cir. 1997); *see also Hopper v. Solvay Pharms.*, 588 F.3d 1318, 1325 (11th Cir. 2009). However, "[i]n contrast to common law

fraud, the FCA "lacks the element of reliance and damages." *Grubbs*, 565 F.3d at 189. "It is adequate to allege that a false claim was knowingly presented regardless of its exact amount; the contents of the bill are less significant because a complaint need not allege that the Government relied on or was damaged by the false claim." *Id.* "To plead with particularity the circumstances constituting fraud for a FCA section [3729(a)(1)(A)] claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. To plead with the requisite particularity a § 3729(a)(1)(B) claim, the complaint need not "allege details of fraudulent bills actually presented to the government." *Id.* at 192. The relator must, however, allege facts linking a scheme to submit false claims to the submission of false claims. *Solvay Pharms.*, 588 F.3d at 1325.

4. The Application of the Pleading Standards to FCA Claims

Although the parties' discussion of Rule 12(b)(6) cites *Twombly* and *Iqbal* as the most recent statements by the Supreme Court under the rule, the arguments do not turn on a claim that the analysis and result in this case are different under those decisions than they would have been earlier. The parties' briefs do not argue whether the facts alleged are sufficient to make the claim of an FCA violation "plausible." Rather, the defendants argue that taking the facts alleged as true, as a matter of law, the FCA does not provide a basis for relief for the promotional activities and remuneration alleged.

The relator does argue for a relaxed application of Rule 9(b). (Docket Entry No. 75, at 24). The cases are clear that Rule 9(b) applies in FCA cases. *Longhi*, 575 F.3d at 468, *Thompson*, 125 F.3d at 903; *Hopper*, 588 F.3d at 1325. The cases also recognize two exceptions that the relator urges. "It is possible that the pleading requirements of Rule 9(b) may be relaxed in certain

circumstances — when, for instance, the facts relating to the fraud are 'peculiarly within the perpetrator's knowledge.'" *United States ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 330 (5th Cir. 2003) (quoting *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 308 (5th Cir. 1999). "Fraud may be pleaded on information and belief under such circumstances." *United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 385 (5th Cir. 2003). But the Fifth Circuit has held that a plaintiff should not be relieved from complying with the Rule 9(b) requirements "where the documents containing the requisite information are in the possession of, and presumably available from, other sources." *United States ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 n.6 (5th Cir. 2008) (citing *Doe*, 343 F.3d at 330); *see also Polansky*, 2009 WL 1456582, at *8 ("The rationale for reducing the pleading burden when information is in the defendant's possession appears to spring from the fact that an adverse party would not willingly divulge incriminating information. Where the information needed to fill out the complaint is in the hands of third parties, rather than defendants, this rationale for reducing the pleading burden does not apply.").

The Eleventh Circuit has held that the pleading standard should not be relaxed for *qui tam* plaintiffs who may have access to information only through discovery in suits where the government refuses to intervene, even though the government would have access to those documents without discovery. *Atkins*, 70 F.3d at 1360 & n.17. The court reasoned:

> The *qui tam* relator bring the action *on behalf of* the federal government. The relator stands in the government's shoes—in neither a better nor worse position than the government stands when it brings suit. Accordingly, we cannot furnish a *qui tam* relator with an easier burden than the government would bear if it intervened and assumed the prosecution of the case. Permitting a *qui tam* relator to go forward with his complaint, when we would not allow the government to proceed, might encourage the government to evade its burden by merely recruiting a willing relator to file a *qui tam* action.

United States ex. Rel. Atkins, 470 F.3d 1350, 1360 (11th Cir. 2006).

The relator argues that in *United States ex rel. Grubbs v. Kanneganti*, the Fifth Circuit relaxed the pleading standard for pleading fraud under the FCA. In *Grubbs*, the Fifth Circuit reversed the district court's dismissal of a *qui tam* suit alleging that psychiatrists billed Medicare and Medicaid for services not performed. 565 F.3d 180, 195 (5th Cir. 2009). The *Grubbs* panel held that a *qui tam* plaintiff does not need to allege "the time, place, and contents of the false representation" in every case. 565 F.3d at 191. The panel reasoned that requiring this level of detail "is one small step shy of requiring production of actual documentation with the complaint" and held that "to plead fraud with particularity . . . a relator's complaint, if it cannot allege details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. *Grubbs* analyzed the Eleventh Circuit's decision in *Clausen*, which required allegations of the "specific contents of actually submitted claims, such as billing numbers, dates, and amounts." *Id.* at 186. Rejecting this requirement, the *Grubbs* court stated as follows:

> [T]he "time, place, contents, and identity" standard is not a straitjacket for Rule 9(b). Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act. We reach for a workable construction of Rule 9(b) with complaints under the False Claims Act; that is, one that effectuates Rule 9(b) without stymieing legitimate efforts to expose fraud. We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

Id. at 190.

The relator argues that this court should relax the pleading standard because she does not have access to certain information. In the Fifth Circuit, the pleading standard is not relaxed when such information is available from third party entities and individuals. *Rafizadeh*, 553 F.3d at 873 n.6. The defendants note that it does not have billing or reimbursement information; doctors, hospitals, and government agencies do. There is no basis to relax the Rule 9(b) pleading standard on this ground under the applicable precedents. *See Polansky*, 2009 WL 1456582, at *8 (refusing to relax the pleading standard in off-label *qui tam* against drug manufacturer because the needed information available was not in the hands of the defendants but in the hands of third parties).

The First Circuit has held that "in situations . . . where the defendant induced third parties to file false claims . . . a more flexible standard applies." *United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 275 (D. Mass. 2010) (quoting *United States ex rel. Duxbury v. Ortho Biotech. Prods.*, 579 F.3d 13, 29 (1st Cir. 2009)). For these claims, "[a] relator can satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details of each false claim." *Id.* If *Grubbs* states a similar approach, it also emphasizes that district courts must look to whether the plaintiff alleges either at least some false claims with particularity or, if she cannot, alleges both particular details of the scheme to submit false claims and reliable indicia that lead to a strong inference that false claims were actually submitted. *Compare United States ex rel. Carpenter*, 723 F. Supp. 2d 395, 408 (D. Mass. 2010) (dismissing allegations of an off-label pharmaceutical kickback scheme because the relator could not "offer any particulars as to names, dates, amounts, or the incentives doctors are alleged to have been offered") *with id.* at 407–08 (denying motion to dismiss off-label prescription reimbursement allegations where the relator alleged a detailed description of eight false claims which included: the patient's identity, the patient's drug history to show that the prescription was

off-label, the date of the claim, the Medicare of Medicaid program to which the bill was submitted, the location of the submitting pharmacy, the dosage, the dollar amount billed, the initials of the pharmacist who filled the prescription, and the name of the doctor who wrote it). *See also Duxbury*, 579 F.3d at 29–30 (finding that relator alleging that defendant caused off-label prescriptions alleged fraud with particularity by identifying eight healthcare providers that submitted false claims, the dates of the false claims, and the amounts of the false claims, but noting that the allegations still presented a "close call"); *United States ex rel. Piacentile v. Sanofie Synthelabo, Inc.*, Civ. A. No. 05-2927, 2010 WL 5466043, at *7–9 (D.N.J. Dec. 30, 2010) (noting that courts have not required the relator to "allege the details of particular claims" when the allegations are that the defendant caused false claims to be submitted, but finding the relator's allegations insufficient under this standard because he could not identify one physician who wrote an off-label description because of the defendant's marketing).

The relator also urges this court to relax the Rule 9(b) pleading standard because the alleged fraud occurred over an extended period of time and consists of numerous acts." *Bristol–Myers Squibb Co.*, 587 F. Supp. 2d at 821 (listing cases). Courts have allowed the plaintiff to "plead the fraudulent scheme with particularity and provide representative examples of specific fraudulent acts conducted pursuant to that scheme." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 509–10 (6th Cir. 2007); *see also Barrett*, 251 F. Supp. 2d at 35 ("While a complaint that covers a multi-year period may not be required by Rule 9(b) to contain a detailed allegation of all facts supporting each and every instance of submission of a false claim, some information on the false claims must be included." (citing *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051 (9th Cir. 2001)). The relator in the present case has not, however, alleged a "representative sample" or even an "instance of submission." *Bledsoe*, 501 F.3d at 509–10; *Barrett*,

251 F. Supp. 2d at 35. Nor has the relator alleged that a specific physician or hospital submitted a false claim. *Willard*, 336 F.3d at 385. Instead, the relator relies only on the allegation that the defendants extensively promoted the FlexView system. The relator has identified no basis to relax the Rule 9(b) pleading standard because the alleged activities extended over years.

Even under a relaxed pleading standard, the relator must still state a factual basis for her assertions. *See United States ex rel. King v. Alcon Labs., Inc.*, 232 F. Supp. 2d 568, 572 (N.D. Tex. 2005) (finding that even under a relaxed pleading standard, the relators failed to plead fraud with particularity because the relator did not identify a single person involved in the alleged fraud, did not did not identify specific fraudulent claims, and did not identify a single date on which fraudulent activity occurred); *United States ex rel. Lam v. Tenet Healthcare*, 481 F. Supp. 2d 673, 688 (W.D. Tex. 2006) (finding that even under a relaxed pleading standard, the relators failed to set forth a factual basis for their beliefs because they failed to name one physician who violated the anti-referral statute; did not specifically identify one fraudulent transaction; and failed to specifically allege the fraud's "when" by alleging only that the fraudulent events occurred "at some point in the 1980s, between 1995 and 2002, and in 1999). *Cf. Rost*, 507 F.3d at 732–33 (recognizing that Rule 9(b) may be satisfied where "although some questions remain unanswered, the complaint as a whole is sufficient to pass muster under the FCA," but upholding dismissal because the relator did not identify specific physicians who submitted claims for reimbursement for off-label prescriptions).

C. The Case Law on Off-Label Marketing as an FDA Claim

Recently, a number of *qui tam* actions alleging FCA violations caused by off-label marketing by drug companies have been filed in federal courts.[12] Both parties discuss three such cases: *United*

[12] *See* Richard C. Ausness, *There's Danger Here, Cherie!: Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-label Uses*, 73 BROOK. L. REV. 1253, 1275–96 (2008) (identifying the

States ex rel. Franklin v. Parke–Davis, 147 F. Supp. 2d 39 (D. Mass. 2001); *United States ex rel. Hess v. Sanofi–Synthelabo Inc.*, No. 4;05CV570MLM, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006); *Hopper v. Solvay Pharms. Inc.*, 588 F.3d 1318 (11th Cir. 2009). In addition, both parties discuss *In re Cardiac Devices Qui Tam Litig.*, a *qui tam* case alleging FCA violations caused by unlawful use of medical devices by hospitals. 221 F.R.D. 318 (D. Conn. 2004).

In *Franklin v. Parke–Davis*, the relator, a doctor formerly employed by Parke–Davis to promote its drug Neurotonin, alleged that Parke–Davis engaged in a "fraudulent scheme to promote the sale of the drug Neurotonin for 'off-label uses' . . . and that this illegal marketing campaign caused the submission of false claims to the Veterans Administration and to the federal government for Medicaid reimbursement." 147 F. Supp. 2d at 43. The FDA approved Neurotonin "for use as an adjunctive treatment for epilepsy in doses from 900 to 1800 mg per day." *Id.* at 45. The relator alleged that Parke–Davis promoted Neurotonin for off-label use "as mono-therapy for epilepsy, for control of bipolar disease, and as treatment for attention deficit disorder." *Id.* Parke–Davis's alleged off-label promotional tactics included using medical liaisons such as the relator to make "exaggerated or false claims concerning the safety and efficacy of Parke–Davis drugs for off-label uses"; rewarding physicians who prescribed large quantities of Parke–Davis drugs with kickbacks; and paying physicians to create "sham" studies urging off-label uses that "had no scientific value." *Id.* at 45–46.

The relator also alleged that "when questions arose concerning the availability of reimbursement for prescriptions for off-label uses of Parke–Davis drugs," Parke–Davis made efforts to conceal the fraud. *Id.* at 46. Medical liasons "were instructed to coach doctors on how to conceal

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FCA as a source of liability for off-label promotion and discussing recent cases).

the off-label nature of the prescription" and Parke–Davis "shredd[ed] documents, falsif[ied] documents, and encourag[ed] medical liaisons to conduct their marketing activities without leaving a paper trail." *Id.*

Parke–Davis moved to dismiss. Unlike the medical device case in which there is FDA approval for general use related to the specific purpose being promoted, there was no dispute as to whether "an off-label prescription submitted for reimbursement is a false claim within the meaning of the FCA." *Id.* at 51. The court granted Parke–Davis's motion in part and denied it in part. *Id.* at 44.

The court found that the complaint met Rule 9(b)'s pleading requirements with respect to submissions to Medicaid because it sufficiently alleged fraudulent schemes to "increase the submission of off-label prescriptions for Neuortonin for payment by Medicaid" and "to induce off-label prescriptions for Neurotonin" by physicians. *Id.* at 48. It reasoned that the relator identified the fraud's "who" by naming Parke–Davis employees who instructed medical liaisons on how to fraudulently promote off-label use of Neurotonin, listing the medical liaisons by name, and identifying the physicians contacted; identified the fraud's "what" by alleging that the off-label promotion resulted in the submission of ineligible claims for reimbursement for off-label use of Neurtonin; identified the fraud's "when" by alleging the term of the relator's employment; and the fraud's "how" by alleging a detailed description of the marketing scheme that included "misleading" materials *Id.* The relator also alleged eleven "specific examples of fraudulent statements which medical liaisons . . . were trained to give to physicians, and did give to physicians, to induce the purchase of Neurotonin for off-label uses." *Id.* In contrast, the court found that the complaint did not sufficiently allege a fraudulent scheme to cause false submissions to the Veterans Administration because it did not "specify which Parke–Davis personnel engaged in this conduct, where such

conduct took place, which VA personnel were involved, or any specific fraudulent statements made to personnel at the [VA]." *Id.* at 50.

With respect to the Medicaid allegations, the court rejected Parke–Davis's causation challenges. Parke–Davis argued that the FCA does not impose liability for violating FDA regulations because such violations do not involve a claim or statement to the government. The court stated:

> It is true that the FCA cannot be used to enforce compliance with every law or regulation . . . the FCA can be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit . . . . Thus, the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a).

Id. at 51–52 (internal citations omitted). The court also rejected Parke–Davis's argument that off-label promotion does not always entail a false statement. Parke–Davis argued that off-label promotion may involve only the distribution of one physician's finding of new drug's use to another physician. The court responded that the relator alleged "more than a mere technical violation of the FDA" by alleging that physicians distributed findings they knew to be false. The court also rejected Parke–Davis's argument that physicians' independent determinations that an off-label prescription provided the best treatment for a patient cut off Parke–Davis's liability because it was an intervening cause. The court responded that because the intervening cause was foreseeable to Parke–Davis, the chain of causation did not break. *Id.* at 51–53. Finally, the court rejected Parke–Davis's argument that its false statements were not "material" to the government's decision to pay. The court noted that "[l]iability under the FCA . . . is not limited only to false statements or claims made directly by

the Defendant to the government," and that the FCA "'reaches beyond claims which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.'" *Id.* at 53 (citing *United States v. Neifert–White Co.*, 390 U.S. 228, 233 (1968)).

However, the *Parke–Davis* court dismissed the relator's kickback allegations. The court rejected the relator's argument that a violation of the antikickback statute is a *per se* violation of the FCA. The court reasoned that though an FCA violation might be based on "'implied certification' [of compliance with the antikickback statute] by virtue of the defendant's participation in the federal program," the relator had "failed to allege that physicians either expressly certified or, through their participation in a federally funded program, impliedly certified their compliance with the federal antikickback statute as a prerequisite to participating in the federal program." *Id.* The court reasoned that "while Defendant's payment of kickbacks may well be illegal," the relator did not allege that "Parke–Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute." *Id.* at 55.

In *Hess*, the relator alleged that Sanofi–Snythelabo's off-label promotion of its drugs Eloxatin — approved for "second line treatment of fourth stage colorectal cancer" — and Elitek — approved for the treatment and prevention of tumor lyses syndrome — caused the submission of false claims for payment for off-label uses. 2006 WL 1064127, at *2. The relator alleged that Sanofi–Synthelabo promoted Eloxatin for treatment in both "first-line" and "adjuvant"[13] settings by training sales representatives to use off-label data when promoting Eloxatin to physicians, creating sales goals impossible to meet without off-label usage, and by providing sales representatives with monographs containing information on adjuvant and first-line trials for Eloxatin. *Id.* at *8. The

[13] An "adjuvant" use of a drug is a use to "enhance the effectiveness of" other medical treatment. WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 56 (Merriam-Webster 1990).

relator further alleged that the data provided to physicians was "immature, unreliable, and misleading." *Id.* With respect to Elitek, the relator alleged that Sanofi–Synthelabo trained its sales representatives to promote off-label uses and pressured the sales representatives to derive a substantial number of sales from off-label use. *Id.* at *6. Sanofi–Synthelabo moved to dismiss. It argued that the relator did not allege any false representations to physicians or the government, did not allege any improper prescriptions, and did not allege that doctors who prescribed the drugs also sought reimbursement from Medicare. Sanofi–Synthelabo also argued that the relator failed to alleged fraud with the required particularity. *Id.* at *4. Specifically as to Eloxatin, Sanofi–Synthelabo argued that because Medicare does not require a physician to specify the stage of cancer in submitting claims for reimbursement, physicians made no false statements in submitting claims for use of Eloxatin to treat colorectal cancer in first-line and adjuvant settings. *Id.* at *8. The court granted Sanofi–Synthelabo's motion to dismiss, addressing the allegations involving each drug separately.

The court dismissed the allegations related to Elitek under Rule 9(b) because the relator failed to allege the "who, what, when, where, and how of fraud." *Id* at *6. The court noted that the relator did not allege "the time or place of the allegedly false representations regarding Elitek," "the nature or content of claims made which were allegedly fraudulent," or "that doctors to whom Plaintiff promoted off-label use of Elitek actually submitted false claims to the Government for off-label uses of this prescription drug." *Id.* The court deemed the relator's allegations "vague" and "conclusory" and dismissed for "lack of the requisite specificity to withstand a motion to dismiss pursuant to either Rule 12(b)(6) or Rule 9(b)." *Id.*

The court also dismissed the Eloxatim allegations because the relator did not allege a "material" misrepresentation. In *United States ex rel. Costner v. United States*, the Eighth Circuit

adopted a materiality requirement for FCA claims, requiring that the misrepresentation have the natural tendency to influence an agency action, the same test the Fifth Circuit adopted in *Longhi*. 317 F.3d 883, 887–88 (8th Cir. 2003). The court accepted Sanofi–Synthelabo's argument that the reimbursement claims did not contain a material false statement because the reimbursement forms did not require that the physician indicate the stage of cancer, only that the patient had cancer. The only statement material to Medicare reimbursement is that the patient had cancer; the government does not inquire further into whether the drug is approved for a particular cancer stage. *Id.* at *7.

The court considered other arguments. It agreed with Sanofi–Synthelabo's argument that the relator did not sufficiently plead the FCA's knowledge requirement because the plaintiff did not allege that the "Defendant deliberately lied nor that the data provided by Defendant either to its sales representatives or to doctors was incorrect or false." *Id.* at *9. The court distinguished the alleged promotion tactics in *Parke–Davis* by noting that "none of the actions which Plaintiff alleges on the part of the Defendant . . . involve conduct which was designed to present *false* information; rather . . . the Defendant sought to disseminate date and information from trials and studies." *Id.* at *10. The court found that the relator did not sufficiently allege false statements to Medicare. The court noted that while typically Medicare reimburses only on-label prescriptions, "such approval is not necessarily a requirement." *Id.* The court also noted that—unlike in *Parke–Davis*—the relevant Medicare administrator chose to apply an exception allowing coverage for off-label prescriptions of Eloxatin and concluded that "because . . . the Medicare administrator included off-label uses of Eloxatin for reimbursement purposes, Plaintiff can prove no set of facts to establish that Defendant violated the FCA." *Id.* at *9. Finally, the court, applying *Parke–Davis*, found that the relator did not allege fraud with the particularity required by Rule 9(b). The court found that the complaint did

not identify the fraud's "who" because it did not "identify doctors whom sales representatives allegedly contacted nor . . . doctors who allegedly made claims for Medicare reimbursement for off-label uses" or the fraud's "how" because it did not provide "examples of the allegedly false information which Defendant allegedly gave its sales representatives." *Id.*

In *Solvay*, the relators alleged that Solvay Pharmaceuticals's off-label promotion of Marinol caused the submission of false claims for reimbursement to Medicare. 588 F.3d at 1321. The FDA approved Marinol, a synthetic form of THC, a hallucinogenic compound found in marijuana, for use as an appetite stimulant for AIDS patients and for the treatment of nausea and vomiting associated with cancer chemotherapy. *Id.* at 1322. The relators alleged that Solvay promoted Marinol for off-label treatment of appetite loss in cancer patients and of nausea in HIV patients. The alleged off-label promotional activities included "a sophisticated marketing plan" and "kickbacks to physicians and other healthcare providers to induce them to prescribe Marinol for off-label purposes." *Id.* at 1323. The district court referred the case to a magistrate judge, who recommended dismissal. The district court adopted the magistrate judge's recommendation and the relators appealed. *Id.* The issue on appeal was whether the complaint, "which did not include allegations of specific false claims or allege that Solvay intended for its statements to influence the government's decision to pay any claims, satisfies the particularity requirements of Rule 9(b)." *Id.*

The Eleventh Circuit upheld the district court's dismissal. In reaching this conclusion, the Eleventh Circuit discussed its decisions in *United States ex rel. Clausen v. Lab Corp. of Am.*, 290 F.3d 1301 (11th Cir. 2002); *United States ex rel. Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005); and *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006). In *Clausen*, the court upheld the district court's dismissal of a complaint alleging the submission of claims for reimbursement for unnecessary laboratory tests even though the complaint "included detailed

allegations of a scheme to overcharge, [] identified the patients who received tests, specified which tests were improper, and set forth the dates on which the tests were performed" because the complaint "failed to provide any information linking the testing schemes to the submission of false claims." *Solvay*, 588 F.3d at 1325 (citing *Clausen*, 290 F.3d at 1303). Absent an allegation linking the schemes to the submission of false claims, the Eleventh Circuit found that the allegations were conclusory. *Id.* (citing *id.*). In *Corsello*, the court upheld the district court's dismissal of a complaint alleging that medical equipment companies engaged in a "kickback and referral scheme to falsify certificates of medical necessity to submit false claims for Medicare payments" because "it did not allege that a specific fraudulent claim was in fact to submitted to the government." *Id.* (citing *Corsello*, 428 F.3d at 1013–14). In *Atkins*, the court upheld the district court's dismissal of a complaint alleging "an elaborate scheme for defrauding the government by submitting false claims" for payments from Medicare for psychiatric services that were not actually rendered. *Id.* (citing *Atkins*, 470 F.3d at 1354). The complaint cited "particular patients, dates and corresponding medical records for services" not eligible for reimbursement. *Id.* (citing *id.* at 1359). In upholding the dismissal, the *Atkins* court reasoned that the relator "failed to provide the next link in the [FCA] liability chin: showing that the defendant *actually submitted* reimbursement claims for the services he described." *Id.* (quoting *id.*). The *Solvay* court noted that unlike *Clausen*, *Corsello*, and *Atkins*, the complaint contained "a highly-detailed compelling statistical analysis [that] rendered inescapable the conclusion that a huge number of claims for ineffective uses of Marinol resulted from [Solvay's illegal marketing] campaign." *Id.* at 1326. Nonetheless, the court upheld the dismissal because it did not "allege the existence of a single actual false claim." *Id.* Under these precedents, the *Solvay*

court upheld the district court's dismissal because the relators did not allege "the actual presentment of a false claim." *Id.* at 1324.

The *Solvay* court also found the allegations insufficient under Rule 9(b) because they did not "identify specific persons or entities that participated in any step of the process. Nor [did] it allege dates, times, or amounts of individual false claims." *Id.* And, even assuming that "when a physician writes an off-label prescription with knowledge or intent that the cost of filling that prescription be borne by the federal government," the allegations were still insufficient because the complaint did not "identify a single physician who wrote a prescription with such knowledge; did not "identify a single pharmacist who filled such a prescription"; and did not "identify a single state healthcare program that submitted a claim for reimbursement to the federal government." *Id.* The court summarized: "We cannot conclude that the Complaint satisfies the particularity requirements of Rule 9(b) by offering 'some indicia of reliability . . . of an actual false claim for payment being made to the government.'" *Id.* (citing *Clausen*, 290 F.3d at 1311 (emphasis removed)). Finally, the *Solvay* court distinguished the allegations from those found sufficient in *United States ex rel. Walker v. R&F Properties of Lake Co., Inc.*, 433 F.3d 1349 (11th Cir. 2005). In *Walker*, the complaint "included allegations of first-hand knowledge that explained why [the relator] believed a specific defendant submitted false or fraudulent claims"; under the facts alleged in *Solvay*, by contrast, "the relators [did] not allege personal knowledge of the billing practices of any person or entity." *Solvay*, 588 F.3d at 1325 (discussing *Walker*, 433 F.3d at 1360).

In re Cardiac Devices discussed an FCA claim based on off-label use of a medical device. Unlike the present suit, that case involved the pre-1995 Medicare regulations that prohibited reimbursement for devices the FDA did not approve for marketing. 221 F.R.D. at 326–27. A sales representative for cardiovascular-device manufacturers alleged that 132 clinical-trial hospitals from

thirty states submitted Medicare reimbursement claims for services involving "nearly sixty different investigational cardiac devices that had not been approved for marketing by the [FDA]" in direct contravention of the manual instructions.[14] *Id.* at 332. After receiving notice of the complaint, the Office of the Inspector General of HHS subpoenaed records from the hospitals and ultimately elected to intervene. *Id.* at 327. The government and the relator moved to sever the action against each hospital and to transfer each to the federal district where the hospital was located. *Id.* at 327. The separate complaints for each hospital generally alleged that the hospitals received cardiac devices the FDA had not approved pursuant to an "Investigation Device Exemption" that restricted their use to "carefully monitored clinical trials . . . to gather evidence of the safety and effectiveness of the devices." *Id.* at 329. The complaints alleged that the hospitals had submitted reimbursement claims to Medicare and Medicaid for using the devices in treatment and received "millions of dollars in Medicare and Medicaid reimbursements." *Id.* at 330. The complaints broke "down the number of procedures performed involving each particular cardiac device." *Id.* For example, the complaint for one hospital stated "that it charged Medicare and/or Medicaid for at least thirty-seven procedures involving prosthetic heart valves manufactured by St. Jude that had not received marketing approval from the FDA." *Id.* The complaints also alleged that the defendant hospitals "were on notice . . . that Medicare considered medical procedures involving cardiac devices that had not been approved for marketing by the FDA . . . to be non-covered and non-reimbursable" and that the hospitals knowingly misrepresented the devices' approval in claims for reimbursement sent to their respective Medicare intermediaries. *Id.*

The defendants filed two motions to dismiss the complaints. The first motion argued that

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[14] A number of the defendant hospitals settled before the court's decision on the motion to dismiss. *Cardiac Devices*, 221 F.R.D. at 326–27.

the complaints did not allege fraud with sufficient particularity. Specifically, the defendants argued that:

> (1) the complaints merely allege a "per se" fraud theory, equating fraud with an alleged violation of the Medicare Hospital Manual and not particular fraudulent misconduct;
>
> (2) the complaints do not identify specific claims submitted to the government and do not allege the "who, what, when, where, and why" of the defendants' allegedly fraudulent misconduct; and
>
> (3) the complaints do not allege facts giving rise to a strong inference of fraudulent intent.

Id. at 331.

In denying the defendant's motion to dismiss, the court first held that the plaintiffs were entitled to a relaxed pleading standard because the alleged fraud involved a "complex scheme" with numerous transactions and "the specific factual information" was peculiarly within the defendants' control. *Id.* at 333–34. By contrast, no such relaxation is warranted under the Fifth Circuit case law. As discussed, the pleading standard is not relaxed when such information is available from third party entities and individuals. *Rafizadeh*, 553 F.3d at 873 n.6. The record shows that in the present case, the defendants do not have billing or reimbursement information; doctors, hospitals, and government agencies do.

The court in *In re Cardiac Devices* rejected the defendant's first argument, that violation of the manual provision's "reasonable and necessary" requirement is only a regulatory violation and not fraud *per se.* The court found that a physician's certification that the use of the device was "reasonable and necessary" was an "underlying condition to payment." *Id.* at 335–36. The court also found that the complaints alleged specific false submissions by the hospitals, including the

"who, what, where, when, and how" of the alleged fraudulent statement.[15] The court cited the Eleventh Circuit's decision in *United States ex rel. Clausen v. Lab Corp. of Am.*, which upheld dismissal of an FCA complaint because the relator did not allege "an actual false claim." 290 F.3d at 1311. The *Cardiac Devices* court noted that the complaints "listed the number of claims" for each device and included "patient lists" provided by the defendant hospitals that, when read in conjunction, "identified the submission of specific claims." *Id.* at 337. The court distinguished *Clausen*:

> This is not a situation where only a general scheme of fraud was alleged that might have resulted in the submission of false claims. Here, the fraudulent scheme was the submission of the claims themselves. This stands in sharp contrast to the complaints in Clausen, which "[a]t most, . . . raise[d] questions about [the defendant's] internal testing policies. But nowhere in the blur of facts and documents assembled by Clausen regarding six alleged testing schemes can one find any allegation, stated with particularity, of a false claim actually being submitted to the Government." 290 F.3d at 1312.

Id. Finally, the court found that the complaints alleged facts giving rise to a strong inference of fraudulent intent. Because the FCA requires only that a defendant act "knowingly," the complaints do not to allege "a specific intent to defraud." *Id.* at 339. Instead, complaints had to allege "'the knowing presentation of what is known to be false' as opposed negligence or innocent mistake." *Id.* (citing *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001) (citing *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996), *cert. denied*, 519 U.S. 865 (1996))).

The defendants' second motion to dismiss argued that the complaints failed to state a claim

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[15] The complaints alleged "who" by identifying the specific hospitals; "what" by identifying the specific claims submitted; "where" as the place where the claims were filed; "when" by providing the "dates of the patients' hospitalizations" or the year annual cost reports were filed; and "how" by detailing the Medicare reimbursement scheme. *Clausen*, 209 F.3d at 337.

for relief under Federal Rule of Civil Procedure 12(b)(6) because they did not allege that the claims were "false or fraudulent." *Id.* at 342. The court first determined that hospitals' requests for payments on form HCFA-1450 (UB-82[16] and UB-92) "clearly constituted the submission of a 'claim'" under the FCA. *Id.* at 343. The court also found that annual Cost Reports the hospitals submitted were claims because they were accompanied by certifications that the reports were "true, correct, and complete and prepared in accordance with applicable instructions." *Id.* at 344. The court held that the allegations of false claims were sufficient under the Second Circuit's approach in *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). The court explained:

> The Second Circuit in *Mikes* held that a claim may satisfy the falsity element of the FCA in one of three ways. It may be factually false if it "incorrectly describes the goods or services provided or a request for goods or services never provided," [274 F.3d] at 697, or it may be legally false because of an express false certification or an implied false certification. *Id.* at 697–98. In *Mikes*, the Second Circuit held an "expressly false claim is . . . a claim that falsely certifies compliance with a particular statute, regulation or contractual terms, where compliance is a prerequisite to payment." *Id.* at 698 (emphasis added). Under an implied false certification theory, the act of submitting a claim for reimbursement itself implies compliance with the governing federal rules that are a precondition to payment. *Id.* at 699 (emphasis added). The Court emphasized that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original). "Liability under the [FCA] may properly be found therefore when a defendant submits a claim for reimbursement while knowing–as that term is defined by the Act, see 31 U.S.C. § 3729(b)–that payment expressly is precluded because of some noncompliance by the defendant."

Cardiac Devices, 221 F.R.D. at 345. The court found that the claims were alleged to be false under the "factually false" and "legally false/expressly false certification" theories. The claims were

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[16] UB-82 forms were used until 1994, when they were replaced by UB-92 forms. *See Cardiac Devices*, 221 F.R.D. at 345.

alleged to be factually false because the forms instructed hospitals "to enter any remarks not shown elsewhere on the bill but which were necessary for proper payment" and to list "[n]on-covered charges." *Id.* The hospitals' failure to state that the procedures performed were experimental, which were non-covered charges, made the claims factually false. The court also found that the claims were "legally false" because "42 U.S.C. § 1395y(a)(1)(A) contains an express condition of payment — 'no payment may be made [under Medicare] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury,'" and that it "'explicitly links each Medicare payment to the requirement that the particular item or service be 'reasonable and necessary.'" *Id.* (quoting *Mikes*, 274 F.3d at 700). The court found that the alleged claims falsely certified compliance and that the certification of compliance was a prerequisite for payment. *Id.* at 346. For the same reasons, the court found that hospitals' certifications on annual Cost Reports that the reports were "true, correct, and complete" falsely certified compliance where compliance was a prerequisite for payment." The court stated:

> The Medicare regulations imposed on defendants the obligation to provide the intermediaries with all information necessary to determine whether payment was due. Critical to this determination would be information concerning whether services were provided for a non-covered item . . .
>
> . . . [I]n submitting their claims, defendants were obligated to seek payment only for those services that were covered. To the extent that they sought payment for services that were not covered, the claims were legally false. The Government has alleged in its complaints that defendants knowingly submitted claims for payment of non-covered services provided in connection with investigational devices that were not reasonable and necessary. These FCA causes of action, as pled, set forth sufficient facts to satisfy the third element, that the claims were false or fraudulent.

Id. at 347.

IV. Analysis

A. The Allegations that the Defendants Violated the FCA by Marketing a Medical Device for Off-Label Use

The relator alleges that the defendants' off-label promotion of the FlexView system for the treatment of atrial fibrillation caused physicians and hospitals to submit claims to the government falsely stating that the use of the FlexView system was "reasonable and necessary" or "medically necessary." *See, e.g.*, *Mikes*, 254 F. 3d at 700–01 (finding that HCFA-1500 forms implicitly certify that requests for reimbursement comply with 42 U.S.C. § 1395y(a)(1)(A)'s requirement that the items and services provided were "reasonable and necessary"). The relator's claim is that the use of the FlexView system for treating atrial fibrillation cannot be medically necessary because it is not FDA approved for such use. *See* (Docket Entry No. 75, at 11) ("Defendants' entire surgical ablation marketing scheme is rendered fraudulent by the absence of FDA approval (and indeed the presence of express FDA disapproval) for the *single specific* use being promoted, namely the use of surgical ablation to treat atrial fibrillation.").

Importantly, there is no allegation that the defendants concealed or misstated the limits of the FDA's approval on the use of the FlexView system. The relator alleges only off-label promotion efforts, including direct training to physicians on using the FlexView system to treat atrial fibrillation, instructions to salespersons to promote FlexView off-label, and promotional materials highlighting the economic benefits to hospitals of treating atrial fibrillation with Flexview.[17] There is no allegation that the defendants represented that the FlexView system was FDA-approved to treat atrial fibrillation. *Compare Parke–Davis*, 147 F. Supp. 2d at 46 (describing Parke–Davis's efforts

[17] The relator argues that an FDA warning letter sent to St. Jude Medical establishes that the defendants misrepresented the scope of FDA approval. (Docket Entry No. 75, Ex. A). The letter admonishes St. Jude for the off-label promotion of surgical ablation to treat atrial fibrillation. It does not reference Boston Scientific or Guidant. The complaint does not allege that Boston Scientific or Guidant misrepresented the scope of FDA approval to doctors or hospitals. The FDA warning letter does not provide a basis to deny the defendants' motion to dismiss.

to conceal the lack of FDA approval).

Unlike the Medicare coverage at issue in *In re Cardiac Devices*, Medicare may cover medically necessary uses of the FlexView system. Medicare contractors may approve coverage for Category B devices. 42 C.F.R. § 405.211(b). The decision on medical necessity is made by individual physicians exercising independent professional judgment based on the knowledge of their particular patients. The cases recognize that off-label use of a drug or medical device is distinct from a medically unnecessary use of that drug or device. *See Buckman*, 121 S. Ct. at 1018; *Polansky*, 2009 WL 1456582, at *6; *Svidler*, 2004 WL 2005781, at *5; *Stephens*, LEXIS 2009 DIST. 101601, at *20. For medical devices like the FlexView system, the relator must allege sufficient facts to support an inference that the use of the device is not "medically necessary" or "reasonable and necessary" under Medicare regulations. The relator acknowledges this in her brief. (Docket Entry No. 75, at 10).

The relator cites *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 n.6 (5th Cir. 2004), in which the court stated that submitting a request for payment "certifies" that "the services shown on the [payment] form were medically indicated and necessary for the health of the patient." *See also* 42 U.S.C. § 13957(1)(A) ("[N]o payment may be made . . . for any expenses . . . which . . . are not reasonable and necessary for the . . . treatment of illness or injury . . . ."). The relator also points to 42 U.S.C. § 1320c-5(a)(3)'s statement that:

> It shall be the obligation of any health care practitioner . . . who provides health care services for which payment may be made . . . to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients of this chapter . . . will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

These authorities state that a procedure must be "medically necessary" but do not further define the term. The authorities cited by the relator do not provide a basis to infer that a reimbursement submission for using the FlexView system to treat atrial fibrillation, even as a stand-alone procedure, cannot be medically necessary or reasonable and necessary because it is not specifically approved for that purpose.

The relator argues that the use of the FlexView system for surgical treatment of atrial fibrillation is by definition not medically necessary because it is viewed as experimental within the scientific community. But Medicare may cover Class II devices even though they "require special controls, such as performance standards or postmarket surveillance, to provide reasonable assurance of safety and effectiveness." 42 C.F.R. §§ 405.201(b), 405.211(b). *Cf.* 42 CFR § 405.209 (stating that "payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA"). The State's Medicare carrier determines "the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation." (Docket Entry No. 58, ¶ 65). The relator does not allege that *any* state has denied coverage for surgical ablation to treat atrial fibrillation, whether as a stand-alone treatment or in connection with other cardiac procedures. Alleging that the use of the FlexView system to treat atrial fibrillation is "experimental" does not allege a basis for an inference that such use of the system is categorically medically unnecessary.

Nor does the relator allege specific false statements by the defendants that the FlexView system is a first-line treatment for atrial fibrillation. The relator alleges that the defendants promoted FlexView to treat atrial fibrillation even though the FDA had not approved this use and emphasizes that the defendants' salespersons trained physicians to use the FlexView system despite the lack of

FDA approval for the specific use of treating atrial fibrillation. These are not statements that the FlexView system is a first-line treatment for atrial fibrillation or that it was FDA approved to treat atrial fibrillation and do not support an inference that the defendants caused physicians and hospitals to submit reimbursement claims for using the FlexView system as a first-line treatment for atrial fibrillation.

In addition, the relator has failed to plead with sufficient particularity the alleged false claims. The relator has not identified specific physicians or hospitals who received the promotions. She has not alleged the "who" or "where" of the alleged fraud. *See, e.g.*, *Thompson*, 125 F.3d at 903. Like the allegations involving false submissions to the Veterans Administration the *Parke–Davis* court dismissed, but unlike the allegations involving Medicaid submissions the court did not dismiss, the relator has not identified any specific physicians who received off-label promotion. *Parke–Davis*, 147 F. Supp. 2d at 48. Nor has the relator identified any physician to whom the defendants promoted FlexView off-label and who also "actually submitted false claims to the Government for off-label uses" of FlexView. *Hess*, 2006 WL 1064127, at *6; *see also Solvay*, 588 F.3d at 1326 (upholding the district court's dismissal because the relators "did not identify specific persons or entities that participated in any step of the process"); *Polansky*, 2009 WL 1456582 (E.D.N.Y. May 22, 2009) (dismissing *qui tam* involving off-label promotion of Lipitor because the plaintiff did not identify any false claims or physicians who were induced to write a prescription for an off-label use). *Compare Cardiac Devices*, 221 F.R.D. at 337 (denying a motion to dismiss where the complaint identified specific hospitals and specific fraudulent claims). These allegations do not plead fraud with the particularity required by the Fifth Circuit's decision in *Thompson*.

The relator argues that the Eleventh Circuit's decision in *Solvay* is inconsistent with the

Fifth Circuit's decision in *Grubbs* because *Solvay* relies on *Clausen* and the Fifth Circuit rejected *Clausen*'s holding that "the minimum indicia of reliability required to satisfy the particularity standard are the specific contents of actually submitted claims." *Grubbs*, 565 F.3d at 186 (citing *Clausen*, 290 F.3d at 1311). But the *Solvay* court did not apply *Clausen*'s rule that the complaint must allege the specific contents of an actually submitted false claim. Instead, *Solvay* upheld the district court's dismissal because the relator did not allege "the existence of a single false claim . . . let alone a false or fraudulent claim." 588 F.3d at 1326.

In *Grubbs*, the court recognized that the Eleventh Circuit has "moved away from *Clausen*'s most exacting language, accepting less billing detail in a case where particular allegations of a scheme offered indicia of reliability that bills were presented." 565 F.3d at187 (citing *Walker*, 433 F.3d at 1360). But the relator has not alleged the type of information that the *Grubbs* relator did. The Fifth Circuit explained in *Grubbs*:

> The complaint sets out the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud. Grubbs describes in detail, including the date, place, and participants, the dinner meeting at which two doctors in his section attempted to bring him into the fold of their on-going fraudulent plot. He alleges his first-hand experience of the scheme unfolding as it related to him, describing how the weekend on-call nursing staff attempted to assist him in recording face-to-face physician visits that had not occurred. Also alleged are specific dates that each doctor falsely claimed to have provided services to patients and often the type of medical service or its Current Procedural Terminology code that would have been used in the bill.

Id. at 191–92. Under *Grubbs*, *Thompson*, and other precedents, the relator's complaint does not sufficiently allege that by promoting off-label use, the defendants caused the submission of false claims and are liable under the FCA.

The relator has alleged a number of unlawful promotional tactics. The cases recognize that

even if a drug or device manufacturer's marketing or promotion activities violate FDA regulations, that is insufficient to plead that the manufacturer caused physicians or hospitals to submit false claims for reimbursement. *See Rost*, 507 F.3d at 732; *Hess*, 2006 WL 1064127, at *6; *Polansky*, 2009 WL 1456582, at *7. In *Parke–Davis*, the relator identified Parke–Davis's unlawful promotional tactics, including using medical liaisons such as the relator to make "exaggerated or false claims concerning the safety and efficacy of Parke–Davis drugs for off-label uses"; rewarding physicians who prescribed large quantities of Parke–Davis drugs with kickbacks; and paying physicians to create "sham" studies urging off-label uses that "had no scientific value." 147 F. Supp. 2d at 45–46. The relator also provided eleven "specific examples of fraudulent statements which medical liaisons . . . were trained to give physicians, and did give to physicians." *Id.* at 48. The court still dismissed the relator's allegations covering the submission of claims to the Veterans Administration for failure to identify "which Parke–Davis personnel engaged in this conduct, where such conduct took place, which VA personnel were involved, or any specific fraudulent statements made to personnel at the VA." *Id.* at 50. Similarly, in *Rost*, the relator alleged that Pharmacia promoted Genotropin off-label through cash payments for off-label studies, rebates and other kickbacks for off-label prescriptions, and off-label marketing materials. 507 F.3d at 723–24. The relator also alleged statistical data demonstrating a likelihood of high volume off-label prescription-writing. *Id.* at 732. The appellate court nonetheless upheld the dismissal:

> It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b).

Id.

In this case, under *Grubbs* and other precedents, the allegations are both insufficient and insufficiently particularized. The claims of an FCA violation by off-label promotion are dismissed, with leave to amend.

B. The Allegations on Upcoding

The relator alleges that the defendants instructed hospitals and physicians to "upcode" stand-alone surgical ablations — minimally invasive, closed-chest procedures — by entering the code associated with open-chest procedures, ICD-9 procedure code 37.33, in reimbursement claims. The relator alleges that physicians and hospitals should have entered procedure code 37.99, which is more appropriate for such minimally invasive procedures. The relator alleges that entering code 37.33 instead of code 37.99 generates a significantly higher Medicare reimbursement and that the defendants' sales representatives "coached hospitals to obtain over-reimbursement of nearly $20,000, or 300% higher than the hospital cost of the procedure each time Defendants' microwave surgical ablation system is used as a stand-alone procedure." (Docket Entry No. 58, ¶ 121). The relator alleges that the defendants' sales presentations highlighted favorable reimbursement rates and identified code 37.33 as the appropriate code for stand-alone surgical ablations, not code 37.99. Because there was an economic incentive to "upcode," because the defendants pointed out the opportunity to do so, and because stand-alone ablation procedures were presumably performed, the relator argues that she has alleged a sufficient basis to support an inference that the defendants caused hospitals to "upcode" and submit false claims to Medicare.

Under the applicable case law authority, the relator has not pleaded this scheme to defraud with sufficient particularity to withstand dismissal. The relator has not identified any hospital or physician who did in fact "upcode" improperly in a Medicare reimbursement submission. These allegations fail to allege information about the "who, what, when, where, and how of the alleged

fraud." *Thompson*, 125 F.3d at 903. And although the Fifth Circuit qualified the "time, place, and contents" requirement in *Grubbs*, the relator's complaint in this case is still deficient.

The cases involving FCA upcoding allegations against physicians support this result. In *United States ex rel. Bledsoe v. Cmty. Health Sys.*, a district court dismissed a relator's allegations that a hospital submitted numerous false claims for reimbursement to Medicare and Medicaid. 501 F.3d 493 (6th Cir. 2007). The appellate court upheld the dismissal even though the relator identified the CPT codes incorrectly entered in reimbursement submissions because the allegations did "not meet the minimum standard of the 'time, place and content of the alleged misrepresentation on which [the injured party] relied.'" *Id.* at 513 (citing *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 643(6th Cir. 2003)). While the relator in this case has alleged codes physicians and hospitals should use in submitting claims for reimbursement for minimally invasive, stand-alone surgical ablation procedures, the relator has not identified any physicians or hospitals that put the incorrect code on a Medicare reimbursement claim. These allegations are insufficient under the applicable case law.

In *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir.2006), the allegations included upcoding. The relator alleged that the defendants submitted claims for, and received, Medicare reimbursement for psychiatric services that were: "(1) not rendered, (2) not medically necessary, (3) the result of improper 'upcoding,' (4) grounded in psychiatric evaluations provided by unqualified staff personnel, (5) based upon 'pre-formed,' predetermined sets of patient evaluations, diagnostic codes, and treatment plans, and (6) provided with substandard levels of care." *Id.* at 1354. The Eleventh Circuit affirmed the district court's dismissal, stating that "the complaint fails rule 9(b) for want of sufficient indicia of reliability to support the assertion that the defendants submitted false claims." *Id.* at 1358–59. Even though the relator cited particular

patients, dates, and corresponding medical records for services he contended were not eligible for government reimbursement, his claim failed because he did not allege facts showing that the defendants actually submitted reimbursement claims for the services he described. "Instead, he portrays the scheme and then summarily concludes that the defendants submitted false claims to the government for reimbursement." *Id.* at 1359.[18] The relator argues that she has alleged "a definite narrative of the motive, strategy, and results of the Defendants' . . . scheme . . . ." (Docket Entry No. 75, at 25). But in the complaint, the relator has not cited "particular patients, dates, and corresponding medical records" for the alleged upcoding. Nor has the relator alleged that any physician or hospital submitted a false claim for reimbursement. These allegations do not plead fraud with the particularity required by Rule 9(b).

One other point is worth noting. Procedure codes and DRGs are part of Medicare's Prospective Payment System (PPS). One court has explained PPS as follows:

> Under PPS, hospitals are reimbursed based on a pre-determined rate for each Medicare admission. The rate depends on each patient's particular diagnosis and other clinical information. Each patient is classified into a Diagnosis Related Group (DRG) that determines the amount of payment. The DRG payment amounts were derived based on average costs incurred in treating particular conditions. By paying a flat rate based on the patient diagnosis, the PPS system gives

[18] Similar results were reached in *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 35 (D.D.C. 2003) (dismissing FCA upcoding allegations because the complaint did not sufficiently "link" the upcoding allegations "with the submission of claims to Medicare"); *United States v. Aggarwal*, No. 6:03-cv-117-Orl-31KRS, 2005 WL 6011259, at *6 (M.D. Fla. Feb. 10, 2005) (dismissing FCA upcoding allegations against a physician because the United States failed to allege that claims were filed in connection with a specific procedure performed and also failed to allege "the names of the patients in whose name claims were filed, claim numbers, the dates of such claims, to whom the claims were made, and what any of the Defendants received as a result"). *Compare United States ex rel. Harris v. Bernard*, 275 F. Supp. 2d 1, 6 (D. D.C. 2003) (denying a motion to dismiss because the relator identified the employees who caused the submission of false claims; pleaded that the fraud began in 1993 and continued to the time of lawsuit; pleaded that the fraud occurred in the defendant's offices; pleaded twelve "sample patients" whose claims did not correspond with their treatment; and pleaded that the defendants provided treating physicians with fee tickets allowing physicians to select only high paying codes).

providers a financial incentive to provide cost-efficient care.

United States ex rel. Digiovanni v. St. Joseph's/Candler Health Sys., 2008 WL 395012, at *6 (S.D. Ga. Feb. 8, 2008) (citing 42 C.F.R. § 412.2(f); Health Care Financing Administration, 65 Fed. Reg. 18434-01 (April 7, 2000); American Hospital Directory, Medicare Prospective Payment System, http://www.ahd.com/pps.html (last visited Nov. 19, 2007)). The PPS is designed to provide an incentive to hospitals to use lower-cost procedures to treat the diagnosis identified in the PPS code. The allegation that the defendants encouraged hospitals to use the FlexView system in part because of the opportunity to profit by performing a lower-cost procedure to treat the diagnosis does not create a reasonable inference that physicians and hospitals knowingly submitted false claims. There must be an allegation that the defendants and the hospitals and physicians knew that using the DRG code 37.33 for stand-alone minimally invasive surgical ablations was always incorrect and that code 37.99 was the only correct code. The complaint fails to state a claim for relief.

C. The Allegations that the Defendants Paid Kickbacks

The relator alleges that the defendants provided remuneration in various forms to hospitals and physicians to induce them to purchase and use the FlexView system, in violation of the antikickback statute, 42 U.S.C. § 1320a-7b(b)(1–2). The relator alleges that compliance with the antikickback statute is a prerequisite to seeking reimbursement under Medicare and that a false certification of compliance is a basis for a claim under the FCA. *See Thompson*, 125 F.3d at 902; *Graves*, 284 F. Supp. 2d at 497. The Fifth Circuit has held that payment of Medicare claims may be "conditioned upon certification of compliance with laws and regulations including the anti-kickback statute." *Id.*; *see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1041–42 (S.D. Tex. 1998) (finding on remand that allegations that the defendant expressly certified compliance with the antikickback statute in annual cost reports

sufficiently states a claim under the FCA because the certifications were a condition of retaining Medicare payments made during the prior year and a condition of continued eligibility for the Medicare program).

> The antikickback statute provides:
>
> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(1–2).

The facts alleged by the relator are insufficient under the applicable case law to state a claim under the certification theory of FCA liability. The cases demonstrate that the basis of liability is the certification of compliance, not the payment or acceptance of remuneration. *See Siewick*, 214 F.3d at 1376–77 (upholding district court's determination on summary judgment that even if the defendants had violated 18 U.S.C. § 207, "a criminal statute aimed at 'revolving door' abuses by former government employees," there was no fact issue as to an FCA violation because defendants were not required to certify compliance with the statute); *Willard*, 336 F.3d at 382–83 (upholding district court's dismissal because the plaintiff only alleged violations of HMO enrollment antidiscrimination laws but did not allege that the United States "conditioned payment . . . on any implied certification of compliance with the anti-discriminatory provisions"); *Roop*, 559 F.3d at 824 (upholding district court's dismissal because the plaintiff alleged only violation of FDA medical-device-reporting regulations by selling defective products but did not allege that certification with these regulations was a prerequisite to payment).

The relator alleges that the defendants paid unlawful remuneration to hospitals and physicians for their use of the FlexView system, that physicians and hospitals accepted the remuneration, and that physicians and hospitals made reimbursement claims to Medicare. However, the relator has not alleged that the defendants caused any physicians or hospital to make false certifications of compliance. In *Parke–Davis*, the relator's failure to make this allegation warranted dismissal. *See* 147 F. Supp. 2d at 55 (noting that the relator did not allege that "Parke–Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute"). Because the relator has not alleged that the defendants caused any hospital or physician to certify compliance with the antikickback statute, these allegations are

dismissed.[19]

Even if the relator sufficiently alleged that the defendants' kickbacks caused false certifications, the relator has not provided reliable indicia that physicians or hospitals actually falsely certified compliance. The relator has not identified the "'who, what, when, where, and how'" the alleged false certifications. *See Lam*, 481 F. Supp. 2d at (citing *Thompson*, 125 F.3d at 903). The relator has not identified a physician or hospital falsely certifying compliance with the antikickback statute in applying for Medicare reimbursement for surgical ablation using the FlexView system; when such a false certification was made; or how such a false certification was made. Instead, the relator has alleged different types of remuneration provided by the defendants and identified certain hospitals and doctors performing stand-alone surgical ablations. These allegations do not provide reliable indicia that there were actual false certifications of compliance. *See id.* at 687 (dismissing allegations of false certifications of compliance with antikickback statute even though the relators named the "who" because the relators did not allege "even one specific illegal referral" or the specific times of the fraud); *Carpenter*, 723 F. Supp. 2d at 405 (dismissing allegations of an off-label pharmaceutical kickback scheme because the relator could not "offer any particulars as to names,

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[19] As noted, the Fifth Circuit has not adopted implied certification as a theory of FCA liability. *Marcy*, 520 F.3d at 389 (citing *Willard*, 336 F.3d at 381–82); *Southland Mgmt. Corp.*, 326 F.3d at 679 (Jones, J. concurring); *Steury*, 625 F.3d at 268. The relator can state a claim that "the defendant has made a false certification of compliance with the statute or regulation, when payment is conditioned on that certification." *Graves*, 284 F. Supp. 2d at 497; *Steury*, 625 F.3d at 269. Whether the relator alleges that the defendants expressly or impliedly certified compliance with the antikickback statute is unclear. The relator alleges: "Either pursuant to provider agreements, claims forms, or other manner, hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations." (Docket Entry No. 58, ¶ 44). The relator does allege that violation of the antikickback statute can cause exclusion from Medicare, but she does not allege any specific certification of compliance. (*Id.* at ¶ 43). *Compare Cardiac Devices*, 221 F.R.D. at 345 (identifying the forms on which the compliance certifications were made, where the forms required certification, and the false statements of certification).

dates, amounts, or the incentives doctors are alleged to have been offered"); *United States ex rel. Kennedy v. Aventis Pharms.*, 610 F. Supp. 2d 938, 945 (2009) (the relators "identified a number of hospitals to which Aventis allegedly gave kickbacks disguised as unrestricted grants to induce their continued use and/or promotion of Lovenox for unapproved indications," but failed to allege "that one or more of the hospitals falsely certified, in connection with a Medicare claim, that it had complied with the anti-kickback statute; the failure to identify "any certification by a hospital," caused dismissal). The relator fails to identify any hospitals or physicians who certified compliance with the antikickback statute. These allegations are dismissed.

D. The Retaliation Allegations

The relator alleges that the defendants retaliated against her for challenging the legality of their marketing practices by firing her. She asserts that this violated both section 3730(h) of the FCA and Illinois law. Section 3730(h), the FCA's antiretaliation provision, states:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

The *prima facie* elements of a retaliation claim under the False Claims Act are that: (1) the employee engaged in protected activity under the statute; (2) the employer knew that the employee engaged in protected activity; and (3) the employer discriminated against the employee because she engaged in protected activity. *Graves*, 284 F. Supp. 2d 487, 510 (S.D. Tex. 2003), *aff'd*, 111 F. App'x 296 (5th Cir. 2004)

Similarly, Illinois law recognizes a tort for "retaliatory discharge." *Zimmerman v. Buchheit*

of Sparta, Inc., 645 N.E.2d 877, 880 (Ill. 1994). "A plaintiff states a valid claim for retaliatory discharge only if she alleges that she was (1) discharged; (2) in retaliation for her activities; and (3) that the discharge violates a clear mandate of public policy." *Id.*

The relator's complaint does not allege sufficient factual allegations for either her FCA or Illinois retaliation claims. *Cuvillier*, 503 F.3d at 401. For both claims, the relator alleges only that she "challenged the legality of the Defendants' . . . marketing techniques both during her initial training and during a national sales meeting" and that she "was reprimanded, harassed and discharged by Defendants as a direct cause of her acts challenging Defendants' marketing approach as unlawful." (Docket Entry No. 58, ¶¶ 127–28). Courts have held that such threadbare recitations of the elements of an FCA retaliation claim do not meet Rule 12(b)(6)'s pleading standard. *See United States ex rel. Davis v. Prince*, 2010 WL 2679761, at *4 (E.D. Va. July 2, 2010) (dismissing FCA retaliation claim when the plaintiff only alleged that "the defendants wrongfully terminated [the relator] for seeking to rectify the abuses occurring in the Jordan offices").[20] Nor do threadbare recitations of the elements of an Illinois retaliation claim meet Rule 12(b)(6)'s pleading standard. *See Fleszar v. Am. Med. Ass'n*, 2010 WL 1005030, at *9 (N.D. Ill. Mar. 11, 2010) (dismissing

[20] Courts have also held that to prevail on an FCA retaliation claim, the plaintiff must do more than "challenge" the defendant; she "must have specifically investigated or complained about the employer making false claims for federal funds, and the employee must show that the employer knew of the investigation or complaint." *See Bouknight v. Houston Ind. Sch. Dist.*, 2008 WL 110427, at *4 (S.D. Tex. Jan. 8, 2008); *United States v. Columbia Healthcare Corp.*, 2005 WL 1924187, at * 13 ("In addition, the protected conduct element requires that a whistleblower must report or investigate attempts to defraud the government."); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 38 (D.D.C. 2003) (nothing that the FCA retaliation provision requires that "an employee be investigating false or fraudulent claims aimed at extracting money from the government." (citing *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996); *Hammack v. Automated Info. Mgmt., Inc.*, 981 F. Supp. 993, 996 (N.D. Tex.1997)); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1055 (N.D. Ill.1998) ("[T]he employee must, at least to some degree, couch her concerns or investigation in terms of funds her employer fraudulently obtained from the government.").

complaint because the plaintiff alleged only that she "was discharged . . . in retaliation for her reporting perceived violations of state and federal law to . . . management and to state and federal agencies"); *United States v. Thorek Hsp. and Med. Ctr.*, 2007 WL 2484333, at *1 (N.D. Ill. Aug. 29, 2007) (dismissing as conclusory allegations that the plaintiff refused to assist doctors to create claims she believed to be false and that she was fired because of her refusal). The relator's allegations do not state a claim for relief under the FCA or Illinois law.

The relator argues that an Illinois district court's decision in *Jones v. Park Forest Coop. IV*, No. 09-C-2653, 2010 WL 748147 (N.D. Ill. Feb. 26, 2010), establishes that allegations that a plaintiff complained about an activity and was discharged plausibly states a claim for relief for retaliatory discharge under Illinois law. In *Jones*, the plaintiff's complaint contained factual allegations. The court, citing the plaintiff's complaint, wrote:

> On December 12, 2006, Tas completed an allegedly false disciplinary report of plaintiff. (*Id.* ¶ 18.) On December 15, 2006, plaintiff complained to Tas about being unfairly disciplined when Sandy Isaac, a bookkeeper employed by the defendant whose job duties included making the health benefit plan payments to the insurance carrier, had not been disciplined for her failure to pay the insurance carrier in a timely manner. (*Id.* ¶¶ 13, 22.) Plaintiff openly demanded reimbursement for out-of-pocket medical expenses incurred as a result of the failure to pay the healthcare insurance premiums. (*Id.* ¶ 61b-c.)
>
> Plaintiff alleges that Isaac, who reported directly to Tas, sought to persuade Tas to terminate plaintiff due to his complaints and his assertion of racial discrimination. (*Id.* ¶¶ 25-26.) After December 15, 2006, plaintiff received false, adverse, work-related performance reports made to justify his subsequent termination. (*Id.* ¶ 23.) In April and May 2007, Tas issued plaintiff official warnings of imminent termination for substandard performance. (*Id.* ¶¶ 44-45.) Shortly thereafter, Tas terminated plaintiff. (*Id.*).

Id. at *1. These allegations provide far more detail than the relator's complaint. *Jones* does not

provide a basis to deny the defendants' motion to dismiss.

The relator also cites three Illinois appellate court decisions to support her contention that allegations that the plaintiff complained and was discharged state a plausible claim for relief. In both cases, the court applied the "fair notice" pleading standard rejected in *Twombly* and *Iqbal*. *See Sherman v. Kraft Gen. Foods, Inc.*, 651 N.E.2d 708, (Ill. App. Ct. 1995) ("Dismissal of a cause of action on the pleadings is only proper where it is clearly apparent that plaintiff can prove no set of facts that would entitle him to recover."); *Paskarnis v. Darien–Woodridge Fire Protection Dist.*, 623 N.E.2d 383, 586 (Ill. Ct. App. 1993) (same); *Russ v. Pension Consultants Co., Inc.*, 538 N.E.2d 693, 696 (Ill. Ct. App. 1989) (same). These cases are inapplicable.

The FCA and Illinois retaliation claims are dismissed.[21]

E. Leave to Amend

The relator requested leave to amend should this court dismiss their complaint. (Docket Entry no. 75). The relator has only amended once, (Docket Entry No. 58), before the filing of the defendants' motion to dismiss. This court grants the relators leave to amend. *See Great Plains Trust Co.*, 313 F.3d at 329; *Adrian*, 363 F.3d at 403. An amended complaint must be filed by April 15, 2011.

V. Conclusion

The defendants' motion to dismiss, (Docket Entry No. 68), is granted, without prejudice.

[21] The defendants also moved to dismiss the relator's Illinois retaliation claims on the basis that the complaint alleges insufficient contacts with that state to justify the application of Illinois law. As the defendants acknowledge in their brief, the complaint contains insufficient facts to resolve this issue.

The relator may amend her complaint by April 22, 2011,

SIGNED on March 31, 2011, at Houston, Texas.

Lee H. Rosenthal
United States District Judge